EXHIBIT A

IN THE CHANCERY COURT OF JACKSON, COUNTY MISSISSIPPI

SINGING RIVER HEALTH SYSTEM; ANDERSON REGIONAL HEALTH SYSTEM; BILOXI HMA, LLC d/b/a MERIT HEALTH BILOXI; CLARKSDALE HMA, LLC d/b/a NORTHWEST MISSISSIPPI MEDICAL CENTER; FIELD MEMORIAL COMMUNITY HOSPITAL d/b/a FIELD HEALTH SYSTEM; JACKSON HMA, LLC, d/b/a MERIT HEALTH CENTRAL; MAGNOLIA REGIONAL HEALTH CENTER, MADISON HMA, LLC d/b/a MERIT HEALTH MADISON; BRANDON HMA, LLC d/b/a MERIT HEALTH RANKIN; WESLEY HEALTH SYSTEM, LLC d/b/a MERIT HEALTH WESLEY; NATCHEZ HOSPITAL COMPANY, LLC d/b/a MERIT HEALTH NATCHEZ; NORTH SUNFLOWER MEDICAL CENTER; RIVER OAKS HOSPITAL, LLC d/b/a MERIT HEALTH RIVER OAKS, VICKSBURG HEALTHCARE, LLC d/b/a MERIT HEALTH RIVER REGION and MERIT HEALTH RIVER REGION WEST; ROH, LLC d/b/a MERIT HEALTH WOMAN'S HOSPITAL; TIPPAH COUNTY HOSPITAL; ALLIANCE HEALTHCARE SYSTEM; MEMORIAL HOSPITAL AT GULFPORT; DELTA REGIONAL MEDICAL CENTER; PROGRESSIVE MEDICAL MANAGEMENT OF BATESVILLE d/b/a PANOLA MEDICAL CENTER; and BOA VIDA HOSPITAL OF ABERDEEN, MS, LLC;

PLAINTIFFS

v.

Case No. 19-1879-TH

NATHAN C. GRACE, JACLYN P. GATLING; LESLIE ROBERSON; AMNEAL PHARMACEUTICALS, LLC; AMNEAL PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; ASSERTIO THERAPEUTICS, INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICALS COMPANIES, INC.; MALLINCKRODT, LLC; MALLINCKRODT PLC; SPECGX, LLC; ALLERGAN PLC; ALLERGAN FINANCE, LLC; ALLERGAN SALES, LLC; ALLERGAN USA, INC.;ACTAVIS LLC; ACTAVIS PHARMA, INC.; ANDA, INC.; H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG CO.; HENRY SCHEIN, INC.; JM SMITH CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CVS INDIANA, LLC; THE KROGER CO.; KROGER LIMITED PARTNERSHIP II; RITE-AID OF MARYLAND, INC.; WALGREEN CO., INC.; WALGREEN EASTERN CO., INC.; WAL-MART, INC.; and WAL-MART STORES EAST, LP.

DEFENDANTS

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> The decade of the 1990s was the era of the blockbuster drug, the billion-dollar pill, and a pharmaceutical sales force arms race was part of the excess of the time … A pharmaceutical Wild West emerged. Salespeople stampeded into offices. They made claims that helped sell the drugs to besieged doctors. Those claims also lead years later to blockbuster lawsuits and criminal cases against their companies.[1]

COMPLAINT

Plaintiffs Singing River Health System, Anderson Regional Health System, Biloxi HMA, LLC d/b/a Merit Health Biloxi, Clarksdale HMA, LLC d/b/a Northwest Mississippi Medical Center, Field Memorial Community Hospital d/b/a Field Health System, Jackson HMA, LLC, d/b/a Merit Health Central, Magnolia Regional Health Center, Madison HMA, LLC d/b/a Merit Health Madison, Brandon HMA, LLC d/b/a Merit Health Rankin, Wesley Health System, LLC d/b/a Merit Health Wesley, Natchez Hospital Company, LLC d/b/a Merit Health Natchez, North Sunflower Medical Center, River Oaks Hospital, LLC d/b/a Merit Health River Oaks, Vicksburg Healthcare, LLC d/b/a Merit Health River Region and Merit Health River Region West, ROH, LLC d/b/a Merit Health Woman's Hospital, Tippah County Hospital, Alliance Healthcare System, Memorial Hospital at Gulfport, Delta Regional Medical Center, Progressive Medical Management of Batesville d/b/a Panola Medical Center, and Boa Vida Hospital of Aberdeen, MS, LLC (collectively, "Plaintiffs") bring this Complaint against Defendants Nathan C. Grace; Jaclyn P. Gatling; Leslie Roberson; Amneal Pharmaceuticals, LLC; Amneal Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Abbott Laboratories; Abbott Laboratories, Inc.; Assertio Therapeutics, Inc.; Endo Health Solutions, Inc.;

[1] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* at 133 (Bloomsbury Press 2015) (hereinafter referred to as "Dreamland").

Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceuticals Companies, Inc.; Mallinckrodt, LLC; Mallinckrodt Plc; Specgx, LLC; Allergan Plc; Allergan Finance, LLC; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc; Anda, Inc.; H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Co.; Henry Schein, Inc.; AmerisourceBergen Drug Corporation; JM Smith Corporation; Cardinal Health, Inc.; CVS Health Corporation; CVS Pharmacy, INC.; CVS Indiana, LLC; The Kroger Co.; Kroger Limited Partnership II; Rite-Aid of Maryland, Inc.; Walgreen Co., Inc.; Walgreen Eastern Co., Inc.; Wal-Mart, Inc.; and Wal-Mart Stores East, LP (collectively "Defendants") under the equitable doctrines of unjust enrichment and the common law of nuisance, seeking abatement of the nuisance created by Defendants, indemnity, and for such other relief as equity may require from Defendants for the harm intentionally and wrongfully done and continuing to be done to Plaintiffs by Defendants, who have been and continue to be unjustly enriched at the expense of Plaintiffs.

INTRODUCTION

I. THE OPIOID CRISIS IN MISSISSIPPI

1. Plaintiffs operate hospitals located throughout Mississippi. The service areas of Plaintiffs' hospitals have been hit hard by the opioid crisis.

2. The opioid epidemic poses an ongoing crisis in Mississippi. In 2017, there were 12.2 drug overdose deaths per 100,000 persons; the majority of which involved an opioid.[2] In 2018, there were 342 reported overdose deaths in the State; 62% were from opioids.[3]

[2] National Institute on Drug Abuse, Mississippi Opioid Summary, (revised May 2019), *available at* https://www.drugabuse.gov/opioid-summaries-by-state/mississippi-opioid-summary (hereinafter referred to as Mississippi Opioid Summary").
[3] Stand Up, Mississippi, Fact Sheet, https://standupms.org/wp-content/uploads/2019/04/Stand-Up-Fact-Sheet-2019.pdf (last accessed July 24, 2019).

3. Opioid abuse has reached epidemic levels in Mississippi. From 2006 to 2012, more than 800 million prescription pain pills were supplied to Mississippi[4]. In 2017, there were 92.9 opioid prescription written for every 100 persons, compared to the average U.S. rate of 58.7 prescriptions, making Mississippi one of the top five opioid prescribing states in the nation.[5] In 2018, there were enough doses of opioids dispensed for every man, woman, and child in Mississippi to have 50 doses each.[6]

4. Recently disclosed data from the DEA's Confidential Automation of Reports and Consolidated Orders System (ARCOS) shows the magnitude of opioid distribution throughout Mississippi and along the Mississippi Gulf Coast.

5. There were 50,978,217 prescription pain pills supplied to Jackson County from 2006 to 2012. That is enough pills for 53 pills per person per year. Defendant Actavis Pharma, Inc. manufactured 28,985,280 of those pills, and Defendant AmerisourceBergen Drug distributed 15,356,920 of those pills.

6. There were 70,190,778 prescription pain pills supplied to Harrison County from 2006-2016, enough for 55 pills per person per year. 33,680,060 of those pills were manufactured by Defendant Actavis Pharma, Inc. and 13,110,230 of the pills were distributed by Defendant Walgreens.

7. There were 12,330,190 prescription pain pills supplied to Hancock County from 2006-2016, enough for 41 pills per person per year. Over half (6,238,100) of those pills were

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[4] Shaleeka Powell, DEA Database Reveals Number of Opioid Prescriptions in Mississippi, WAPT (July 23, 2019), *available at* https://www.wapt.com/article/dea-database-reveals-number-of-opioid-prescriptions-in-mississippi/28472472.
[5] Mississippi Opioid Summary, *supra* n. 2.
[6] Stand Up, Mississippi, Opioids 101, https://standupms.org/learn/opioids-101/ (last accessed July 24, 2019).

manufactured by Defendant Actavis Pharma, Inc., and 3,606,450 of those pills were distributed by Defendant Smith Drug Company.

8. From 2010-2011, there were nearly 10,000 opioid related hospitalizations in Mississippi.[7]

9. The progression from prescription opioids to the use of illicit drugs, particularly injectable heroin, is well documented, with approximately 75% of heroin users reporting that their initial drug use was through prescription.[8] As Mississippi citizens who become addicted to prescription opioids have predictably migrated to illicit, but less expensive, opioids, namely heroin and fentanyl, overdoses have dramatically increased.[9]

10. On August 14, 2017, Governor Phil Bryant issued an executive order declaring the opioid epidemic an emergency in Mississippi.[10]

11. Opioids have endangered public health in Mississippi even beyond addiction and overdose. Addicts who are not killed by drug addiction experience a variety of health consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community including health care and substance abuse treatment costs – a substantial portion of which were provided by Plaintiffs – as well as other costs borne by the community, increased costs and burdens imposed on the criminal

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[7] Mississippi Morbidity Report, Miss. Dep't. of Health, Vol. 31, No. 7, Dec. 2015, *available at* https://msdh.ms.gov/msdhsite/_static/resources/6472.pdf.
[8] Theodore J. Cicero, PhD et al., *The Changing Face of Heroin Use in The United States: A Retrospective Analysis of The Past 50 Years*, JAMA Psychiatry (2014); 71(7):821-826, doi:10.1001/jamapsychiatry.2014.366, *available at* https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.
[9] New Online Tool Uses Data to Show Impact of Opioids, Oct. 9, 2016, https://nkyhealth.org/2016/10/09/new-onlinetool-uses-data-to-show-impact-of-opioids/?search=opioid.
[10] Miss. Exec Order No. 1403 (Aug. 14, 2017), *available at* https://www.governorbryant.ms.gov/Executive%20Orders/EO%201403.pdf.

justice system and the costs associated with the lost productivity of addicts.[11] Mississippi Attorney General Jim Hood has brought separate lawsuits against opioid manufacturers and distributors for flooding Mississippi communities with dangerous prescription drugs.[12]

12. Children have been especially vulnerable to the opioid epidemic. Along with overdose deaths, the number and rate of neonatal abstinence syndrome ("NAS") – a condition suffered by babies born to mothers addicted to opioids – has also increased dramatically in Mississippi. From 2010 through 2011, there were 151 NAS-related hospital discharges among infants in Mississippi.[13] On average, a child suffering from NAS will stay in the hospital twice as long as a non-NAS child.[14] On average, the costs for treating a child suffering from NAS is over three times more than a child who does not have NAS.[15] Infants with a NAS-related diagnoses are more likely to have respiratory disorders, low birth weight, sepsis, and seizures.[16] These infants will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs – a process so painful that it traps many adults on opioids. When untreated, NAS can be life-threatening.

13. Children are also left orphaned by family members lost to addiction. As of January 2018, there were over 6,000 children in foster care in Mississippi, half of which have

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[11] Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, Am. Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf
[12] Mississippi Sues Opioid Distributors Over Crisis, AP News, Dec. 6, 2018, *available at* https://www.apnews.com/5e453e7c41ef4bd996c3ab01b6b0aa9f.
[13] Hospitalizations for Neonatal Abstinence Syndrome in Mississippi, 2010-2011, Miss. Dep't of Health, Nov. 2016, *available at* https://msdh.ms.gov/msdhsite/_static/resources/7001.pdf.
[14] *Id.*
[15] *Id.*
[16] *Id.*

parents suffering from drug dependence, a high percentage of which is attributable to opioids.[17] Children are also injured by the removal from their homes due to opioid abuse and addiction.

14. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of naloxone—an antidote to opioid overdose. In one year alone (2017-2018), 58 lives in Mississippi were saved through the administration of naloxone by first responders.[18]

15. Mississippi has seen an increase in blood-borne diseases caused by intravenous drug use, including hepatitis C and human immunodeficiency (HIV). In 2015, 3.6% of new HIV cases in males and 4.2% in females was attributed to intravenous use of opioids.[19] Nationally, 68.6% of new hepatitis C cases are attributed to intravenous drug use. If untreated, hepatitis C continues to be transmitted, including in childbirth. Hepatitis C can ultimately cause liver cancer, fibrosis, or cirrhosis, and is the leading cause of liver transplants in the country.

16. Across Mississippi, families and communities face heartbreaking tragedies that cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; other have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and hospitals such as Plaintiffs.

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[17] Desare Frazier, Opioid Abuse Takes Toll On Children and Fostercare System, MPB, Jan. 11, 2018, *available at* http://www.mpbonline.org/blogs/news/2017/12/21/opioid-abuse-takes-toll-on-children-and-fostercare-system/.

[18] Terese Apel, Mississippi First Responders With Narcan Save 58 Lives In A Year, Clarion Ledger, Aug. 8, 2018, *available at* https://www.clarionledger.com/story/news/local/2018/08/08/mississippi-first-responders-narcan-save-58-lives-year/935091002/.

[19] Mississippi Opioid Summary, *supra* n. 2.

II. THE OPIOID CRISIS NATIONALLY

17. The United States is in the midst of an opioid epidemic caused by Defendants' unlawful marketing, sale, and distribution of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and the loss of life.[20] The United States constitutes 4.6% of the world's population, but consumed 80% of the world's opioid supply in 2011.[21] According to the Centers for Disease Control and Prevention ("CDC"), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.[22]

18. It is undisputed that opioids are both addictive and deadly. Between 1999 and 2014, more than 165,000 Americans died of opioid overdose.[23] Deaths related to opioids are accelerating. In 2011, the CDC declared that prescription opioid deaths had reached "epidemic levels."[24] That year, 11,693 people died of prescription opioid overdoses.[25] Since then,

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[20] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

[21] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, https://www.colorado.gov/pacific/sites/default/files/Psycholigical%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf (citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Abuse*, PAIN PHYSICIAN JOURNAL, 14:E119-E131, (2011), *available at*, https://www.painphysicianjournal.com/current/pdf?article=MTQ0NQ%3D%3D&journal=60.

[22] Centers for Disease Control and Prevention, *Prescribing Data, available at* https://www.cdc.gov/drugoverdose/data/prescribing.html, (last accessed August 1, 2018).

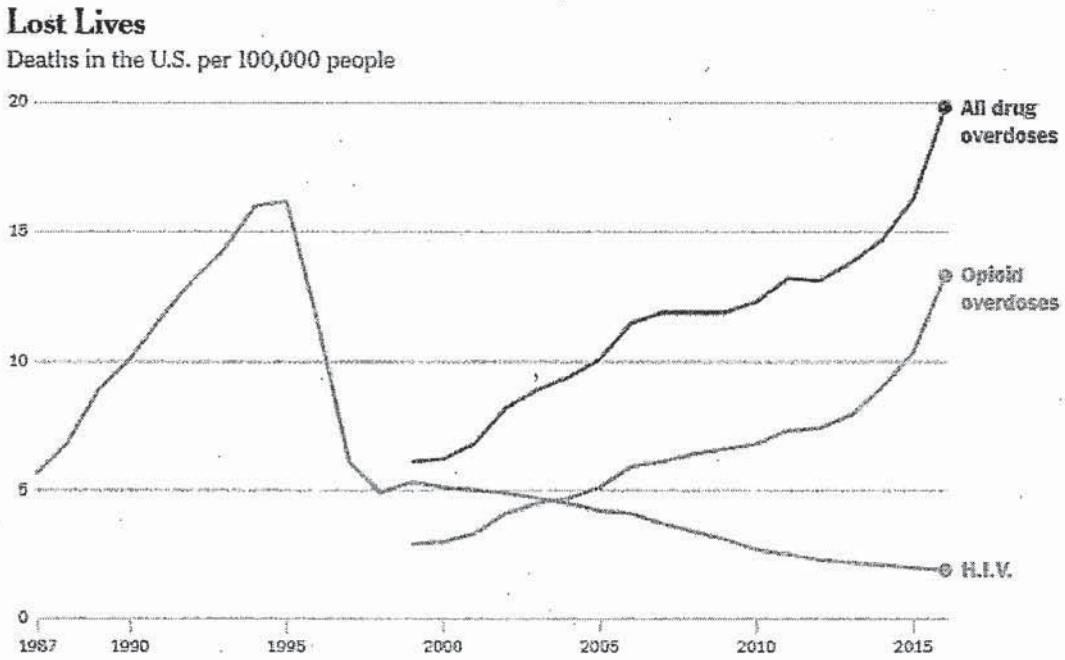
[23] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) Morbidity and Mortality Weekly Report (Mar. 2016), at 2, *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf (hereinafter "Dowell, CDC Guideline").

[24] Press Release, Centers for Disease Control and Prevention: Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html (hereinafter "Prescription Painkiller Overdoses at Epidemic Levels").

[25] Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999-2011*, 166 NCHS Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf.

prescription opioid deaths have *more than quadrupled*, reaching 47,600 Americans in 2017—more than ten times the number of Americans who died in the entire Iraq War.[26]

19. According to the CDC, opioid overdoses killed more than 45,000 people, nationally, over a 12-month timeframe that ended in September 2017. It is already the deadliest drug epidemic in American history.[27] If current trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.



Note: Drug overdose data available since 1999. Source: Centers for Disease Control and Prevention | By THE NEW YORK TIMES.[28]

[26] U.S. Dep't of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019), https://www.hhs.gov/opioids/about-the-epidemic/index.html; German Lopez, *2017 was the worst year ever for drug overdose deaths in America*, VOX, Aug. 16, 2018, https://www.vox.com/science-and-health/2018/8/16/17698204/opioid-epidemicoverdose-deaths-2017.
[27] The Editorial Board, *An Opioid Crisis Foretold*, THE NEW YORK TIMES (April 21, 2018), https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html.
[28] *Id.*

20. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[29] In many cases, heroin abuse starts with prescription opioid addiction. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[30] For most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes. Filling an opioid prescription is a significant risk factor for overdose.[31]

21. According to the CDC, the United States is currently seeing the highest overdose death rated ever recorded.[32] Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes.[33] As opioid-related deaths increase, the life expectancy in the United States decreases.[34]

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[29] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. End. J. Med. 1480 (Apr. 14, 2016), doi: 10.1056/NEJMsr1601307, https://www.nejm.org/doi/full/10.1056/NEJMsr1601307.

[30] Dart, Richard C. et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015), DOI: 10.1056/NEJMsa1406143, *available at* https://www.nejm.org/doi/full/10.1056/nejmsa1406143.

[31] Dowell, CDC Guideline, *supra* n. 23, at 22-24.

[32] Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months, says CDC*, The GUARDIAN (March 6, 2018). https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc.

[33] Wayne A. Ray et al., *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315(22):2415-2423, JAMA (Jun. 2016), doi:10.1001/jama.2016.7789, *available at* https://jamanetwork.com/journals/jama/fullarticle/2528212.

[34] National Center for Health Statistics, Life Expectancy, *available at* https://www.cdc.gov/nchs/fastats/life-expectancy.htm, (last accessed August 1, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids, (March 18, 2018), https://www.cdc.gov/media/releases.2018/p0329-drug-overdose-deaths.html.

22. On October 28, 2017, the President of the United States declared the opioid crisis a public health emergency.[35]

23. This suit takes aim at the primary cause of the opioid crisis: A false narrative marketing scheme, in which the distributors joined and conspired, involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase demand for and sale of opioids and opioid prescriptions.

24. On the demand side, the Defendants who manufacture, sell and market prescription opioid painkillers (the "Marketing Defendants") precipitated the crisis. These opioids have various brand names and generic names, and include "OxyContin," fentanyl, hydrocodone, oxycodone, and others mentioned in this Complaint. Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients.

25. The Marketing Defendants relentlessly and methodically—but untruthfully—asserted that the risk of addiction was low when opioids were used to treat chronic pain and overstated the benefits and trivialized the risk of the long-term use of opioids. However, opioids are extremely addictive. Studies have found diagnosed opioid dependence rates in primary care settings as high as 26%.[36] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.[37] Because opioids cause tolerance and

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[35] Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, THE NEW YORK TIMES (Oct. 26, 2017), https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

[36] Dowell, CDC Guideline, *supra* n. 23.

[37] Joseph A. Boscarino et al., *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6:83-91, Substance Abuse and Rehabilitation (Aug. 2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/; *see*

dependence, patients who take the drugs for even a short time become a physiologically captured market. According to the U.S. Department of Health and Human Services, more than two million Americans are opioid-dependent.[38] The difficulty in stopping use is particularly true for patients first prescribed an extended release opioid. Patients who initiated treatment on an extended release opioid – such as OxyContin – have a 27.3% likelihood to be using opioids one year later, and a 20.5% likelihood of using opioids three years later.[39] Whether in the end a patient meets the clinical definition of addiction or is simply dependent and unable to stop using opioids, once opioids are prescribed for even a short period of time, patients are hooked.

26. Opioids pose high risks for children and adolescents. Most of the use in this population is off-label as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse. The misuse of opioids in adolescents strongly predicts the later onset of heroin use.[40] Nonetheless, the 2016 CDC guidelines found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

27. The Marketing Defendants' goal was simple: dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pain, such as back pain

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also Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3):185-94, Journal of Addictive Diseases (Sept. 2011), *available at* https://www.ncbi.nlm.nih.gov/pubmed/21745041 (showing a 34.9% lifetime opioid use disorder).

[38] U.S. Dept. of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019), *available at* https://www.hhs.gov/opioids/about-the-epidemic/index.html.

[39] Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66(10):265-269, Morbidity and Mortality Weekly Report (Mar. 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm.

[40] Dowell, CDC Guideline, *supra* n. 23.

and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

28. The Supply Chain Defendants—as defined *infra* in paragraph 196, including the Distributor Defendants and National Retail Pharmacies Defendants, saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities, and flooded affected areas with opioids while knowing they were contributing to, but profiting from, widespread addiction and human misery. The Supply Chain Defendants, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered and fill prescriptions without scrutiny or hesitation, normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout communities in Mississippi.

29. Defendants succeeded. Opioid abuse has quickly become one of the nation's most pressing health management issues, not only because of its toll on patients, but increasingly because of the financial impact on hospitals and the rest of the healthcare system.[41]

30. The Marketing Defendants and the Supply Chain Defendants extract billions of dollars of revenue from the addicted American public while hospitals sustain tens of millions of dollars in losses caused as a result of the reasonably foreseeable consequences of the prescription opioid addiction epidemic. In fact, Defendants depend on hospitals to mitigate the health consequences of their illegal activities – at no cost to Defendants – thereby permitting Defendants to perpetuate their wrongful scheme. Defendants knew that but for the hospitals providing at least some aspect of a safety net, the number of overdose deaths and other related

[41] Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse, (last accessed on August 1, 2018).

health consequences arising from opioid addictions would have been far greater than actually occurred, and the public outcry and political backlash threatening their profitmaking activities would have been swifter and far more certain.

31. The deceptive marketing campaign of the Marketing Defendants and Distributor Defendants substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages 30 and 44, and nearly 30% of the population over 45 have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include a prescription of an opioid.

32. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including Mississippi. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[42]

33. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors [m]any

[42] *America's Addition to Opioids: Heroin and Prescription Drug Abuse*, U.S. Senate, Caucus on International Narcotics Control, 113th Cong., at 3 (May 14, 2014) (statement). Testimony of Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, *available at* https://www.hdsl.ord/?abstract&did=754557.

of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[43]

34. In a 2016 report, the CDC explained that "[o]pioid prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[44] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[45]

35. Defendants' practice of continually filling opioid prescriptions, including from suspicious prescribers, and failing to report suspicious orders of opioids has enabled an oversupply of opioids to communities, including communities in the regions that Plaintiffs serve. The Distributor Defendants had financial incentives to distribute higher volumes of Opioid and not report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit.

36. Further, either explicitly or implicitly, all Defendants in this action worked together to stifle the reporting of suspicious orders. This is because even one defection and

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[43] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *available at* http://www.turntheriderx.org/ (last accessed July 23, 2018).
[44] Rose A. Rudd, et al., Centers for Disease Control and Prevention, Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 (Jan. 1, 2016), Morbidity and Mortality Weekly Report, 64(50);1378-82, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.
[45] *Id.*

reporting to the DEA could have reduced the overall quantity of opioids allowed to be dispensed within the United States. Therefore, to maximize profits, the Defendants worked together to ensure oversupply of the market.

37. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of Naloxone—the antidote to opioid overdose.

38. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that is typically used in veterinary medicine to sedate elephants and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. "People have to understand there's absolutely zero use for humans. None. There's no use in humans unless you're trying to kill them."[46]

III. THE IMPACT OF OPIOIDS ON MISSISSIPPI HOSPITALS

39. Hospitals—legally and morally—are compelled to act and treat patients with opioid- related conditions[47] and, as a result, are directly and monetarily damaged by the opioid epidemic. In addition to the cost of the opioid drugs themselves, hospitals have incurred and continue to incur millions of dollars in damages for the costs of uncompensated care as a result

[46] Evan Schriber, *Carfentanil Death Has Law Enforcement Warning of Danger*, TUCSON NEWS NOW (Apr. 16, 2018) *available at* http://www.tucsonnewsnow.com/story/37971249/carfentanil-death-has-law-enforcement-warning-of-danger (last accessed July 23, 2018).

[47] "Opioid-related conditions" include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; Neonatal Abstinence Syndrome (NAS) or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, Hepatitis-C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiff's records as related to opioid use and abuse.

of the unlawful marketing, distribution, and sale of opioids. Arguably, more than any other institution, hospitals directly bear the brunt of the opioid crisis.

40. Plaintiffs are struggling from the relentless and crushing financial burdens caused by the epidemic of opioid addiction.

41. The effects of the opioid epidemic on hospitals may soon become even worse. The coverage rules under the Affordable Care Act ("ACA") are in transition, thus creating the possibility of increased costs for hospitals for treatment of opioid-addicted patients admitted under the Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd.[48]

42. Plaintiffs encounter patients with opioid addiction on a daily basis. They must deal with patients who have serious medical conditions that require extra care and expense because the patients are addicted to opioids.

43. The statistics are startling. Adult hospitalizations due substantially to opioid addiction related medical conditions doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.[49]

44. Between 2005 and 2014 there was a dramatic increase nationally in hospitalizations involving opioids: the rate of opioid-related inpatient stays increased 64%, and the rate of opioid-related emergency department ("ED") visits nearly doubled.[50]

45. The average health care costs for those diagnosed with an opioid use disorder were eight times higher than those without an opioid use disorder.[51] Use of opioids are associated

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[48] American Hospital Association, *AHA Priorities to Address the Opioid Crisis*, https://www.aha.org/guidereports/2018-03-02-aha-priorities-address-opioid-crisis, (last accessed August 1, 2018).

[49] *Id.*

[50] Audrey J. Weiss, et al, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

with numerous other side effects including gastrointestinal impacts, delayed recovery from injury, cognitive impacts, endocrine impacts, hyperalgesia (increased sensitivity to pain), increased risks of fractures, gastrointestinal bleeding, hospitalization among the elderly, tolerance (need for increasing dose to maintain effect), dependence (causing withdrawal if stopped), and addiction.[52]

46. The cost to hospitalize those with opioid addiction has more than tripled in a decade, up to nearly $15 billion in 2012. Similarly, the number of patients hospitalized due to the effects of these drugs surged by more than 72% in 2012, although overall hospitalizations during that time stayed relatively flat.[53]

47. Private insurance covers only a portion of those costs. The burden is carried by hospitals, patients, and government programs.[54] In 2012, hospitals provided almost $15 billion for opioid-related inpatient care, more than double of what they billed in 2002.[55] A substantial portion of these costs were under-insured or unreimbursed.

48. In 2012, an average hospital stay for a patient with an opioid-related condition cost about $28,000 and only about 20% of the hospital stays related to those incidents were covered by private insurance. The number increased to $107,000 if there was an associated infection, with merely 14% covered by insurance.[56]

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[51] Alen G. White, PhD, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in Journal of Managed Care Pharmacy, Vol. 11, No. 6 July/August 2005, at 469.
[52] Teater, *supra* n. 21 (citing Leonard Paulozzi et al., *CDC Grand Rounds Prescription Drug Overdoses – a U.S. Epidemic*, 61 Morbidity and Mortality Weekly Report 10 (2012)).
[53] Marty Stempniak, *Opioids Add to a Sharp Rise in Hospitalizations, Costs*, (May 5, 2016), https://www.hhnmag.com/articles/7231-opioids-contribute-to-a-sharp-rise-in-hospitalizations-health-care-costs. (last accessed on July 11, 2018).
[54] *Id.*
[55] Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/.
[56] *Id.*

49. Patients with complex opioid addiction-related histories (medically and psychosocially) often cannot get treatment at skilled nursing facilities if they are discharged by hospitals.

50. The cost of treating opioid overdose victims in hospital intensive care units jumped 58% in a seven-year span. Between 2009 and 2015, the average cost of care per opioid overdose admission increased from $58,000 to $92,400. This was during a period where the overall medical cost escalation was about 19%. This cost increase also highlights a troubling trend: overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.[57]

51. Pregnant women and their children have been significantly impacted by the opioid epidemic. There are negative consequences of drug use for pregnant women including increased risks of assault and abuse, miscarriage, and contracting hepatitis or HIV. Each year, thousands of infants are exposed to opioids while in the womb. Infants who are chronically exposed to opioids and other drugs will often experience a constellation of withdrawal signs after birth, collectively referred to as NAS.

52. The rates of opioid abuse during pregnancy have increased nationally and in Mississippi. There has been an almost four-fold increase in admissions to NICUs for NAS over the past decade: from seven cases per 1,000 NICU admissions in 2004, to 27 cases per 1,000 NICU admissions in 2012.

53. The misrepresentations of Marketing Defendants, Distributor Defendants and others led area health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, the Marketing Defendants and

[57] Casey Ross, *The Cost of Treating Opioid Overdose Victims is Skyrocketing*, STAT NEWS (August 11, 2017), https://www.statnews.com/2017/08/11/opioid-overdose-costs/.

Distributor Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These harms were compounded by supplying opioids beyond what the market could bear, funneling so many opioids into Mississippi communities that the only logical conclusion was that the product was being diverted and used illicitly. The massive quantities of opioids that flooded into Mississippi as a result of Defendants' wrongful conduct has devastated communities across this State, including the communities served by Plaintiffs.

IV. FINANCIAL IMPACT OF DEFENDANTS' ACTIVITIES ON PLAINTIFFS

54. Over the years, Plaintiffs have responded to the changing demands of rural healthcare. But the opioid epidemic has challenged their leadership skills, taxed their resources, and threatened their ability to provide quality health care to all in need.

55. Plaintiffs have treated, and continue to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) hepatitis C, HIV and other infections occurring as a result of intravenous drug use; (4) neonatal treatment in their NICU for babies born opioid-dependent, for which treatment is specialized, intensive, complex, lengthy and highly expensive; and (5) psychiatric and related treatment for patients with opioid addiction in need of mental health treatment programs.

56. Plaintiffs have incurred and continue to incur substantial unreimbursed costs for their treatment of patients with opioid-related conditions. These patients with opioid-related conditions seek treatment from Plaintiffs as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiffs' monetary losses with respect to treatment of these patients were and are foreseeable to Defendants and were and are the proximate result of Defendants' acts and omissions specified herein.

57. Plaintiffs also have incurred and continue to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid affected. Surgical procedures on opioid affected patients have been and are complicated and costly and require special protective measures and related prescription drugs.

58. Additionally, individuals with opioid addiction have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems in an effort to obtain opioids. Plaintiffs have incurred and continue to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise attempting to treat these individuals.

59. The costs incurred by Plaintiffs are the direct and proximate result of the false narrative campaign described below and the opioid epidemic created and engineered by Defendants.

60. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the increase in the use of opioids would result in a corresponding epidemic of patients with opioid-related conditions going to hospitals for treatment, including to Plaintiffs. It was foreseeable to Defendants that Plaintiffs would suffer substantial monetary losses because of the opioid epidemic, because hospitals are on the front line of treatment for these patients and must bear the additional costs of treatment.

61. It was also foreseeable that Defendants would face claims from hospitals for their costs from treating opioid-related conditions.

62. Plaintiffs have purchased and continue to purchase and administer opioids marketed and sold by Defendants. Defendants have marketed and continue to market their opioid products directly to Plaintiffs, their pharmacy representatives and their doctors. Defendants

directly marketed their opioid products through the false narrative. Plaintiffs are direct customers and victims of Defendants' false, deceptive, and unfair marketing of opioids described hereafter.

63. Plaintiffs have purchased opioids from Defendants, have used them as falsely and deceptively marketed by Defendants, and have suffered damages as a direct and proximate result of Defendants' acts and omissions as described in this Complaint. As a result, Defendants were unjustly enriched.

64. Plaintiffs bring this action seeking restitution and equitable remedies for losses that they have incurred as a direct and proximate result of Defendants' false, deceptive, and unfair marketing of prescription opioids. Such damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

65. Plaintiffs bring this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were unlawful.

66. Plaintiffs also bring this suit against the Supply Chain Defendants of these highly addictive drugs. In addition to participating in the false narrative campaign described below, the Supply Chain Defendants (along with the Manufacturers) unlawfully breached their legal duties under Mississippi law to monitor, detect, investigate, report, and refuse to fill suspicious orders of prescription opiates, which enabled the manufacturers' deceptive advertising to increase sales and distribution of their products to hospitals, including Plaintiffs.

V. THE ROLES OF DEFENDANTS IN CAUSING AND PERPETUATING THE OPIOID CRISIS

67. The Marketing Defendants' push to increase opioid sales worked. Through publications and websites, endless streams of sales representatives, "education" programs, and other means, Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

68. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors and retail suppliers, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know should be necessary for legitimate medical uses, while failing to report, and take steps to halt, suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

69. From the day they made the pills to the day those pills were consumed in each community, the Marketing Defendants had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring those doctors into prescribing their products by arguing, among other things, that no one should be in pain, especially chronic pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme

worked, although perversely, and through it the Marketing Defendants caused their profits to soar as more and more people became dependent on opioids.

70. Defendants systematically and repeatedly disregarded the health and safety of the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

71. Corporate greed and callous indifference to the known, serious potential for human suffering and death have caused this public health crisis. Defendants unleashed a healthcare crisis that has had far-reaching financial and social consequences in this country, including opioid addiction and death.

72. The Marketing Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo addiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long-term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; and (8) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse, addiction and death.

73. The Marketing Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Marketing Defendants for their support of the Marketing Defendants' marketing messages.

74. The Marketing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). The Marketing Defendants then worked together with those KOLs and Front Groups to profoundly influence, and at times control, the sources that doctors, and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Marketing Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

75. Each Marketing Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.[58]

JURISDICTION AND VENUE

76. Jurisdiction and venue are proper in this district pursuant to Miss. Code Ann. §§ 13-3-57, 11-11-3 and Article 6, Section 159 of the Mississippi Constitution because this action arises in equity, and because each Defendant 1)conducts or conducted business in Mississippi; 2)

[58] *See* Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed August 1, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines.

purposefully direct or directed their actions toward Mississippi; 3) solicited and continue to solicit business, and 4) performed and continue to perform business services, such as marketing, advertising, promoting and distributing their product in Mississippi; and/or have the requisite minimum contacts with Mississippi necessary to constitutionally permit the Court to exercise jurisdiction. .

77. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

PARTIES

I. PLAINTIFFS

78. Plaintiff Singing River Health System is a community owned not-for-profit health system organized under the laws of the State of Mississippi, with its principal place of business in Pascagoula, Mississippi. Singing River Health System has two hospitals: Singing River, located in Mississippi, and Ocean Springs Hospital, located in Ocean Springs, Mississippi.

79. Plaintiff Alliance Healthcare System is a public benefit corporation organized under the laws of the State of Delaware, with its principal place of business in Holly Springs, Mississippi.

80. Plaintiff Anderson Regional Health System is a public non-profit corporation organized under the laws of the State of Mississippi, with its principal place of business in Meridian, Mississippi.

81. Plaintiff Biloxi HMA, LLC is a Mississippi limited liability company d/b/a Merit Health Biloxi with its principal place of business in Biloxi, Mississippi.

82. Plaintiff Clarksdale HMA, LLC is a Mississippi limited liability company d/b/a Northwest Mississippi Medical Center with its principal place of business in Clarksdale, Mississippi.

83. Plaintiff Field Memorial Community Hospital d/b/a Field Health System is a public non-profit corporation organized under the laws of the State of Mississippi, with its principle place of business in Centreville, Mississippi.

84. Plaintiff Jackson HMA, LLC is a Mississippi limited liability company d/b/a Merit Health Central with its principal place of business in Jackson, Mississippi.

85. Plaintiff Magnolia Regional Health Center is a public non-profit corporation organized under the laws of the State of Mississippi, with its principal place of business in Corinth, Mississippi.

86. Plaintiff Madison HMA, LLC is a Mississippi limited liability company d/b/a Merit Health Madison with its principal place of business in Canton, Mississippi.

87. Plaintiff Memorial Hospital at Gulfport is a not-for-profit medical complex organized under the laws of Mississippi with its principal place of business in Gulfport, Mississippi.

88. Plaintiff Brandon HMA, LLC is a Mississippi limited liability company d/b/a Merit Health Rankin with its principal place of business in Brandon, Mississippi.

89. Plaintiff Wesley Health System, LLC is a Delaware limited liability company d/b/a Merit Health Wesley with its principal place of business in Hattiesburg, Mississippi.

90. Plaintiff Natchez Hospital Company, LLC is a Delaware limited liability company d/b/a Merit Health Natchez with its principal place of business in Natchez, Mississippi.

91. Plaintiff North Sunflower Medical Center is a Mississippi Community Hospital formed and operated under Miss. Code §§ 41-13-10 *et seq.*, and its principal place of business is in Ruleville, Mississippi.

92. Plaintiff River Oaks Hospital, LLC is a Mississippi limited liability company d/b/a Merit Health River Oaks with its principal place of business in Flowood, Mississippi.

93. Plaintiff Vicksburg Healthcare, LLC is a Delaware limited liability company d/b/a Merit Health River Region and Merit Health River Region West with its principal place of business in Vicksburg, Mississippi.

94. Plaintiff ROH, LLC is a Mississippi limited liability company d/b/a Merit Health Woman's Hospital with its principal place of business in Flowood, Mississippi.

95. Plaintiff Tippah County Hospital is a public non-profit corporation organized under the laws of the State of Mississippi, with its principal place of business in Ripley, Mississippi.

96. Plaintiff Delta Regional Medical Center is a community, not-for-profit hospital organized under the laws of Mississippi, with its principal place of business in Greenville, Mississippi.

97. Plaintiff Progressive Medical Management of Batesville d/b/a Panola Medical Center is a Mississippi limited liability company, with its principal place of business in Batesville, Mississippi.

98. Plaintiff Boa Vida Hospital of Aberdeen, MS, LLC is a Mississippi limited liability company, with its principal place of business in Batesville, Mississippi.

II. DEFENDANTS

A. Marketing Defendants

1. Purdue

99. Non-Party Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

100. Non-Party Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and is the general partner of Purdue Pharma, L.P.

101. Non-Party The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Non-Parties Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company are collectively referred to as "Purdue" or the "Purdue Entities."

102. The following Non-Parties, all members of the Sackler family that beneficially owns Purdue, have served on the Board of Purdue during the relevant times indicated in parenthesis:

a. Richard Sackler (at all pertinent times until 2018)[59], a resident of Florida;

b. Beverly Sackler (all pertinent times until 2017), a resident of Connecticut;

c. David Sackler (2012-18), a resident of New York;

d. Ilene Sackler Lefcourt (all pertinent times), a resident of New York;

e. Jonathan Sackler (all pertinent times), a resident of Connecticut;

f. Kathe Sackler (all pertinent times), a resident of Connecticut;

g. Mortimer D.A. Sackler (all pertinent times), a resident of New York[60]; and

[59] Beverly Sackler left the Board in 2017. Defendants Richard, David and Theresa Sackler left the Board in 2018. Defendants Jonathan Sackler, Ilene Sackler Lefcourt, Kathe Sackler, and Mortimer D.A. Sackler remain on the Board.

h. Theresa Sackler (all pertinent times until 2018), a resident of the United Kingdom.

103. The foregoing Non-Parties (collectively, the "Sackler Co-Conspirators") controlled Purdue's misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, the Sackler Co-Conspirators, at all pertinent times, constituted a majority of Board, which gave them full power over Purdue. They directed and otherwise participated in Purdue's deceptive sales and marketing practices, sending hundreds of orders to executives and other employees.

104. While the Sackler Co-Conspirators relinquished their officer titles in or around 2003 to try to shield themselves from future criminal and civil liability, they remained Purdue's owners, in control of its Board of Directors, and thus in firm control.

105. At all pertinent times, at least through the end of 2018, the Sackler Co-Conspirators controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise

[60] References to "Mortimer D.A. Sackler" in this Complaint are to Mortimer David Alfons Sackler. Mortimer Sackler's father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

representatives face to face. In connection with a single meeting in 2011, for example, sales and marketing staff scrambled to prepare responses to questions from the Sackler Co-Conspirators as follows: Mortimer D.A. Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients;" Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert; and Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

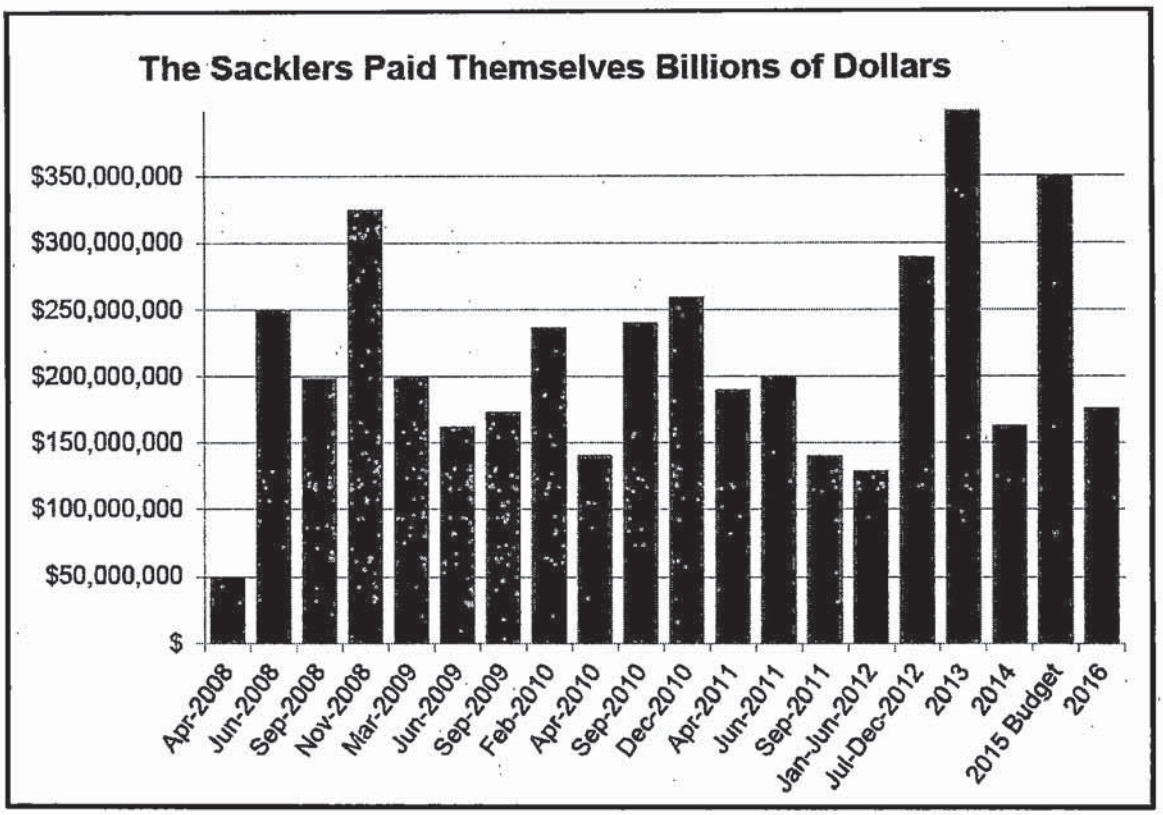
106. The Sackler Co-Conspirators' micromanagement was so intrusive that staff begged for relief. Non-Party Rusell Gasdia wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." To convince the Sackler Co-Conspirators to make him CEO, Non-Party Craig Landau wrote a plan that he titled: "SACKLER PHARMA ENTERPRISE." He started by admitting that the Sackler Co-Conspirators in fact controlled the company like chief executive officers. The family ran "the global Sackler pharmaceutical enterprise … with the Board of Directors serving as the 'de-facto' CEO."

107. The Sackler Co-Conspirators concealed their extensive involvement at all costs. In 2000, the Sackler Co-Conspirators were warned that a reporter was "sniffing about the OxyContin abuse story." The Sackler Co-Conspirators put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that "deflects attention away from the company owners." More recently, in November 2016, staff prepared statements to the press denying the Sackler Co-Conspirators' involvement in Purdue. Their draft claimed: "Sackler family members hold no leadership roles in the companies owned by the family trust." A staff member reviewing the draft knew what was up and commented with apparent sarcasm: "Love the … statement." Staff eventually told the press: "Sackler family members hold no

management positions." Some employees worried about the deception. When journalists asked follow-up questions about the Sackler Co-Conspirators, communications staff deliberated about whether to repeat the "no management positions" claim. They double-checked that Purdue's top lawyers had ordered the statement. Then they arranged for one of the Sackler Co-Conspirators' foreign companies to issue it, so U.S. employees would not be blamed: "The statement will come out of Singapore."

108. Most of all, the Sackler Co-Conspirators cared about money. Millions of dollars were not enough. They wanted billions. They cared more about money than about patients, or their employees, or the truth. In 1999, when employee Michael Friedman reported to Richard Sackler that Purdue was making more than $20,000,000 per week, Richard replied immediately, at midnight, that the sales were "not so great." "After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?" Missives of this nature from Richard to Purdue's ostensible management were a routine, if not daily, occurrence. There was no such thing as enough.

109. From the money that Purdue collected as a result of its wrongful conduct, they paid themselves and their family billions of dollars. From the 2007 convictions (of certain Purdue officers) until 2018, the Sackler Co-Conspirators voted dozens of times to pay out Purdue's opioid profits to their family - in total ***more than four billion dollars.***



110. When the Sackler Co-Conspirators directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Mississippi. Purdue and the Sackler Co-Conspirators tracked revenue from Mississippi.

111. In order to enhance their own and Purdue's social standing and prestige, the Sackler Co-Conspirators endowed many cultural, educational and scientific institutions, many of which bear their family name, including many academic programs at Harvard University and Tufts University in Massachusetts, the New York Academy of Sciences, Columbia University, Dia Art Foundation, the Metropolitan Museum of Art and the Guggenheim art museum, all in New York, London's Victoria and Albert Museum, and the Louvre in Paris. There is a Sackler gallery at the Princeton University Art Museum and Sackler museums at Harvard University and Peking University in Beijing. The Sackler Co-Conspirators and their relatives include many prominent New York and international socialites.

112. Non-Parties John Stewart (CEO from 2007 to 2013), Mark Timney (2014 to 2017), a resident of Connecticut, and Craig Landau (2017 to the present), a resident of Connecticut, each directed Purdue's deception as CEO of Purdue Pharma Inc. and Purdue Pharma L.P. Non-Party Russell Gasdia, a resident of Massachusetts, carried out the misconduct as Vice President of Sales and Marketing at all pertinent times until June 2014. The Purdue executives named in this paragraph are collectively referred to as the "Purdue Officer Co-Conspirators."

113. Defendant Nathan C. Grace is a resident of Jackson County, Mississippi who was employed by Purdue. In 2016, Defendant Grace was ranked third in the nation for sales of Butrans, an opioid pain patch manufactured by Purdue.

114. Defendant Jaclyn P. Gatling is a resident of Madison, Mississippi who was employed by Purdue. In 2016, Defendant Gatling was ranked fourth in the nation for sales of Butrans, an opioid pain patch manufactured by Purdue.

115. Defendant Leslie Roberson is a resident of Pontotoc, Mississippi who was employed by Purdue. In 2016, Defendant Roberson ranked 98th in the nation for sales of Butrans, an opioid pain patch manufactured by Purdue. Defendants Grace, Gatling, and Roberson are referred to herein as the "Purdue Sales Representative Defendants."

116. The Sackler Co-Conspirators, the Purdue Officer Co-Conspirators and the Purdue Sales Representative Defendants are collectively referred to as the "Purdue Individual Defendants." The Non-Party Purdue Entities, the Non-Party Sackler Co-Conspirators, and the Purdue Individual Defendants are collectively referred to at times as "Purdue Conspirators."

117. The Purdue Individual Defendants all actively participated in the common law torts and statutory violations of Purdue and benefited therefrom. The tortious conduct of the

Purdue Individual Defendants was not, and could not have been through the exercise of due diligence, known to the public until their conduct was detailed in recent court filings by the Attorney General of Massachusetts.

118. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including to Plaintiffs. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

119. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – one of the largest settlements with a drug company for marketing misconduct. In the same year, Purdue settled with 27 states for its Consumer Protection Act violations regarding the Purdue's extensive off-label marketing of OxyContin and Purdue's failure to adequately disclose abuse and diversion risks associated with the drug. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year. Substantially all of the Sackler Co-Conspirators (all of those except David Sackler) were heavily involved in the conduct that led to the fines and criminal convictions in 2007. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed a decade of misconduct,

which led to criminal convictions, a judgment of this Court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing, purposeful, reckless, and intentional.

120. Each of the Purdue Individual Defendants acted directly and through agents to transact business and cause injury in Mississippi.

121. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators voted for and/or directed sales representatives to go door-to-door, making thousands of visits to doctors in Mississippi. Although they did not knock on the doors to clinics and family practices themselves, these individuals voted for and/or ordered sales representatives to deceptively promote Purdue's dangerous drugs in person, as a central facet of their deceptive marketing scheme that killed hundreds of people in Mississippi.

122. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators voted for and/or directed payments to Mississippi doctors to promote Purdue's drugs.

123. The Sackler Co-Conspirators and Purdue Officer Co-Conspirators all directed the dissemination of tens of thousands of copies of unfair or deceptive marketing materials to doctors and other health care providers throughout Mississippi for the purpose of getting more and more prescribers to put their patients on Purdue's drugs for longer and longer periods of time at higher and higher doses. These individuals voted for and/or managed a chain-of-command causing these mailings in Mississippi because they meant increased sales and profits for the Sackler Co-Conspirators and their executives.

124. This misconduct caused tortious injury in Mississippi by killing hundreds of people and injuring many more.

2. Teva and Associated Companies

125. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. Is traded on the New York Stock Exchange (NYSE: TEVA). In its most recent Form 10-K filed with the Securities and Exchange Commission, Teva Ltd. stated that it is the leading generic drug company in the United States. Teva Ltd. operates globally, with significant business transactions in the United States. In 2018, its gross profit from North American operations was $4.979 million.

126. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Ltd. Defendant.

127. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

128. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its "specialty medicines" division. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva

Ltd.'s logo.[61] Teva USA's parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon and Teva USA's sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including inter alia sales of Fentora.[62] Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[63] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[64] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a $425 million fine.[65]

129. Teva USA also sells generic opioids in the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Ltd., Teva USA's parent company based in Israel, acquired in August 2016.

130. Teva Ltd., Teva USA, and Cephalon are referred to herein as "Teva."

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[61] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last accessed August 1, 2018).
[62] Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.
[63] *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009)*, ACTIQ PI/Med Guide, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last accessed August 1, 2018).
[64] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011)*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last accessed August 1, 2018).
[65] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

131. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Mississippi, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

132. Defendant Watson Laboratories, Inc. ("Watson") is a Nevada corporation with its principal place of business in Corona, California.

133. Defendant Actavis Pharma, Inc. ("Actavis Pharma") is a Delaware corporation with its principal place of business in New Jersey.

134. Defendant Actavis LLC (f/k/a Actavis Inc.) ("Actavis LLC") is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Watson, Actavis Pharma and Actavis LLC are collectively referred to as "Actavis."

135. Defendant Teva Ltd. acquired ownership of Actavis in 2016. Prior to that transaction, Actavis was owned by Defendant Allergan plc.

136. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

137. Actavis made thousands of payments to physicians nationwide including in Mississippi, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

3. Janssen and Associated Companies

138. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

139. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

140. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

141. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had been part of J&J's opium processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

142. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

143. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho- McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

144. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

145. Janssen made thousands of payments to physicians nationwide, including in Mississippi, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

146. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.[66] Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document. The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

147. The "*Every Day Health Care Compliance Code of Conduct*" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "*Pharmaceutical Companies of Johnson & Johnson*" and as one of the "*Johnson & Johnson Pharmaceutical Affiliates.*" It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Mississippi, ostensibly for activities including

[66] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

4. Endo and Associated Companies

148. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

149. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

150. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

151. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc.

152. Endo Health Solutions Inc., Endo Pharmaceuticals Inc. and Par Pharmaceutical (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

153. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from

2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012.

154. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a "serious outbreak" of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray to an injectable.[67] In response to the FDA's request, Endo removed Opana ER from the market in July 2017, the first time the agency had ever moved to pull an opioid medication from sale.[68] Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

155. Endo made thousands of payments to physicians nationwide, including in Alabama, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

5. Abbott Laboratories

156. Defendant, Abbott Laboratories, is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott Laboratories and Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott."

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[67] Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (hereinafter "FDA Requests Removal of Opana ER").

[68] Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er. (hereinafter "Endo Provides Update on Opana ER").

157. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to the co-promotional agreement with Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

158. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006.

159. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

160. Abbott and Purdue's conspiring with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in an October 28, 2016, article from Psychology Today entitled *America's Opioid Epidemic*:

> Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.... One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco

(PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent.[69]

6. Amneal

161. Defendant Amneal Pharmaceuticals, LLC ("Amneal LLC") is a Delaware limited liability company with its principal place of in New Jersey.

162. Defendant Amneal Pharmaceuticals, Inc. ("API") is a Delaware corporation with its principal place of business in New Jersey. API is the managing member of Amneal LLC, and conducts and exercises full control over all activities of Amneal LLC.[70]

163. API and Amneal LLC are referred to herein as "Amneal."

164. At all relevant times, Amneal has sold prescription drugs including opioids in Mississippi and across the United States.

7. Assertio Therapeutics, Inc.

165. Defendant Assertio Therapeutics, Inc. ("Assertio") is a Delaware corporation with its principal place of business in Lake Forest, Illinois. Assertio describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Assertio develops, markets, and sells prescriptions drugs in Mississippi and across the United States. Assertio acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

8. Mallinckrodt Entities

166. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of

[69] American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, Psychology Today, Oct. 28, 2016, https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic.
[70] *Id.*

Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC (together with Mallinckrodt plc and SpecGx, LLC, "Mallinckrodt") is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant SpecGx, LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and to Plaintiffs. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

167. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

168. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it

manufactures. Mallinckrodt also estimated, based on IMS Health[71] data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[72]

169. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

170. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (Hydromorphone hydrochloride, extended release), Roxicodone (Oxycodone hydrochloride), Xartemis XR (Oxycodone hydrochloride and acetaminophen), Methadose (Methadone hydrochloride), Generic (Morphine sulfate, extended release, Morphine sulfate oral solution, Fentanyl transdermal system, Oral transmucosal fentanyl citrate, Oxycodone and acetaminophen, Hydrocodone bitartrate and acetaminophen, Hydromorphone hydrochloride, Hydromorphone hydrochloride, extended release, Oxymorphone hydrochloride, Methadone hydrochloride. Schedule III: Buprenorphine and naloxone. Unscheduled: Naltrexone hydrochloride.

171. Mallinckrodt made thousands of payments to physicians nationwide, including in Mississippi, ostensibly for activities including participating on speakers' bureaus, providing

[71] "IMS Health was a [provider of] information, services and technology for the healthcare industry, including U.S. physician prescribing data." It has changed its corporate form and is now known as "IQVIA."
[72] Mallinckrodt plc 2016 Annual Report (Form 10-K), *available at* http://www.mallinckrodt.com/investors/annual-reports/.

consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids

9. Allergan and Associated Companies

172. Defendant Allergan plc ("Allergan") is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Shares of Allergan are traded on the New York Stock Exchange (NYSE: AGN). In its most recent Form 10-K filed with the SEC, Allergan plc stated that it does business in the United States through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which generated nearly 80% of the company's $15.8 billion in net revenue during the year ended December 31, 2018.

173. Before (the entities defined above as) Actavis was sold to Teva Ltd. in August 2016, Actavis was part of the same corporate family as Allergan and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan and Actavis. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares was converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

174. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

175. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc. The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

176. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

177. Defendant Allergan plc has, at all times, exercised control over these marketing and sales efforts and profits from the sale of its subsidairies' products ultimately inure to its benefit, including those sales by Actavis during the period of its ownership and control by Allergan. Allergan is or has been in the business of manufacturing, selling, promoting, and/or

distributing both brand name and generic opioids throughout the United States, including to Plaintiffs.

178. Collectively, the Purdue Individual Defendants, Actavis, Amneal, Teva, Janssen, Assertio, Endo, Abbot, Allergan and Mallinckrodt are referred to as "Marketing Defendants."

B. Distributor Defendants

179. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants are engaged in "wholesale distribution," as defined under Mississippi law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiffs' communities.

1. AmerisourceBergen Drug Corporation

180. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including to Mississippi. AmerisourceBergen is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

181. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

182. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare

providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."[73]

2. Anda, Inc.

183. Defendant Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva Ltd. acquired Anda from Defendant Allergan plc (i.e. Defendant Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Mississippi and within the communities served by Plaintiffs.

3. Cardinal

184. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of $121.5 billion.

185. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over $120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Mississippi, and has distributed opioids nationwide.

[73] AmerisourceBergen, 2016 Summary Annual Report, http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb (last accessed August 1, 2018).

4. H. D. Smith, LLC

186. Defendant H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. ("H. D. Smith") through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Mississippi and the community served by Plaintiffs. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith Wholesale Drug Co. has been restructured and is currently doing business as H. D. Smith, LLC. H.D. Smith LLC's sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D. Smith. At all relevant times, H. D. Smith distributed prescription opioids throughout the United States including in Mississippi.

5. Henry Schein Entities

187. Henry Schein, Inc. (Henry Schein) describes its business as providing a products and services to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein, Inc. is incorporated in Delaware, with its principal place of business located in Melville, New York.

188. Henry Schein distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

189. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within Mississippi.

190. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

6. JM Smith Corporation

191. J M Smith Corporation is a Delaware corporation with its principal place of business in Spartanburg, South Carolina. Smith Drug Company is a division of J M Smith Corporation responsible for operating J M Smith Corporation's pharmaceutical distribution business. J M Smith Corporation and Smith Drug Company are referred to as "Smith Drug" throughout this Complaint.

192. At all relevant times, Smith Drug was in the business of distributing pharmaceutical products to consumers within Mississippi.

C. National Retail Pharmacies

1. CVS

193. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island.

194. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island.

195. Defendant CVS Indiana, L.L.C. is an Indiana limited liability company with its principal place of business in Rhode Island.

196. CVS Health, CVS Pharmacy and CVS Indiana are collectively referred to as "CVS." CVS distributed prescription opioids throughout the United States, including in Mississippi.

2. The Kroger Co.

197. Defendant The Kroger Co. is an Ohio corporation with headquarters in Cincinnati, Ohio.

198. Defendant, Kroger Limited Partnership II is an Ohio limited partnership with its principal office located in Columbus, Ohio.

199. The Kroger Co. and Kroger Limited Partnership II are collectively referred to as "Kroger." Kroger operates 2,268 pharmacies in the United States, including in Mississippi. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Mississippi.

3. Rite-Aid of Maryland, Inc.

200. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. ("Rite Aid"), is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in Mississippi (at least until such time as its stores in Mississippi were acquired by Walgreens in or around 2018).

4. Walgreens

201. Defendant Walgreen Co., Inc. ("Walgreen Co.") is an Illinois corporation with its principal place of business in Deerfield, Illinois. Defendant Walgreen Eastern Co., Inc. ("WEC") is a New York corporation with its principal place of business in Deerfield, Illinois.

202. Walgreen Co. and WEC are collectively referred to herein as "Walgreens." At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Alabama.

5. Wal-Mart, Inc.

203. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Arkansas.

204. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

205. Wal-Mart, Inc. and Wal-Mart Stores East, LP are collectively referred to as "Wal-Mart." At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in Mississippi.

206. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart are referred to as "National Retail Pharmacies."

207. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

208. The Distributor Defendants and the National Retail Pharmacies are collectively referred to as the "Supply Chain Defendants."

D. Defendants' Agents and Affiliated Persons

209. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

210. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiffs, who therefore sues these Defendants by

fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint to show their true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

FACTUAL BACKGROUND

I. THE HISTORY OF OPIOIDS

211. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

212. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.[74]

213. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

214. Mississippi law imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Miss. Code Ann. §§ 41-29-1115, 41-29-117. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence.

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[74] Martin Booth, *Opium: A History*, at 20 (Simon & Schuster Ltd. 1996).

215. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Subsys (a product of nonparty and co-conspirator, Insys Therapeutics, Inc. ("insys")), are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

216. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

217. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium,

pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

218. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

219. As one doctor put it, the widespread, long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

II. THE OPIOID EPIDEMIC

220. Prescription opioids have become widely prescribed. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[75]

221. Despite the enormous number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.[76] Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among

[75] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52-e59 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/.

[76] Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 JAMA 872-882 (2018), doi: 10.1001/jama.2018.0899, https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true.

single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.[77]

222. In 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.[78]

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[77] Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), DOI: 10.1001/jama.2017.16190, https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true.

[78] *See* Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

223. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers – which, at the molecular level and in their effect, closely resemble heroin - are forty times more likely to be addicted to heroin.[79] According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.[80]

224. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. The drug is so powerful that it is now being used to execute prisoners on death row.[81]

225. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[82]

226. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[83]

227. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[84]

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[79] *See* Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last accessed August 1, 2018).
[80] Nat'l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf.
[81] Smith, Mitch. *Fentanyl Used to Execute Nebraska Inmate, in First for U.S.*, (Aug. 14, 2018), https://www.nytimes.com/2018/08/14/us/carey-dean-moore-nebraska-execution-fentanyl.html.
[82] Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: http://dx.doi.org/10.15585/mmwr.mm655051e1, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.
[83] *See* Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

228. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[85] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[86]

229. In 2016, the President of the United States officially declared an opioid and heroin epidemic.[87]

III. CONGRESSIONAL RESPONSES TO THE OPIOID CRISIS

230. Congressional interest in the opioid crisis has been intense. Multiple committees in both the House and Senate have conducted dozens of hearings exploring the issue from almost every angle, including effects on the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Congressional efforts culminated in the passage of the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act," or the "SUPPORT for Patients and Communities Act." This Bill passed the House by a vote of 396-14 on June 22, 2018, passed the Senate by a vote of 99-1 on September 17, 2018, and was signed into law by the President on October 24, 2018. Among other provisions, the Bill made it easier to intercept drugs being shipped into the country, authorized new funding for more comprehensive treatment, sped up

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[84] *See* Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, http://www.nejm.org/doi/full/10.1056/NEJMra1507771, (hereinafter "Volkow & McLellan").

[85] *Id.*

[86] *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013* (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, *available at* https://www.ncbi.nlm.nih.gov/pubmed/27623005.

[87] *See* Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week"), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf.

research on non-addictive painkillers, and provided for broader coverage for substance abuse under Medicare and Medicaid regulations that have occasionally stood in the way of treatment. Congressional interest in the issue is ongoing..

THE MARKETING DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

231. The opioid epidemic did not happen by accident.

232. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

233. Each Marketing Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize, or materially understate the risks of opioids while overstating the benefits of using them for chronic pain.

234. The Marketing Defendants have disseminated these common messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led

by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

235. The Marketing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[88] In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[89] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

236. The Marketing Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

237. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance. The harm and endangerment to the public health, safety, and the environment created by this public nuisance is ongoing and has not been abated.

238. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be abated by,

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[88] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

[89] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *supra* n. 43.

inter alia, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

239. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are must do so. It is the manufacturer of a drug that has primary responsibility to ensure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities to ensure that their products and practices meet state controlled substances and consumer protection laws and regulations, exist independent of any FDA or DEA regulation. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

I. THE MARKETING DEFENDANTS' FALSE AND DECEPTIVE STATEMENTS ABOUT OPIOIDS

240. The Marketing Defendants' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low;

b. To the extent there is a risk of addiction, it can be easily identified and managed;

c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;

d. Blaming addicts as "abusers" of opioids;

e. Opioid withdrawal can be avoided by tapering;

f. Opioid doses can be increased without limit or greater risks;

g. Long-term opioid use improves functioning;

h. Alternative forms of pain relief pose greater risks than opioids;

i. A version of Oxycontin marketed by Purdue was effective in providing 12-hour pain relief; and

j. New formulations of certain opioids successfully deter abuse.

241. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

242. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

A. Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low

243. Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

244. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

245. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[90] and the risk substantially increases with more than three months of use.[91] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[92]

1. Purdue and Abbott's Misrepresentations Regarding Addiction Risk

246. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as

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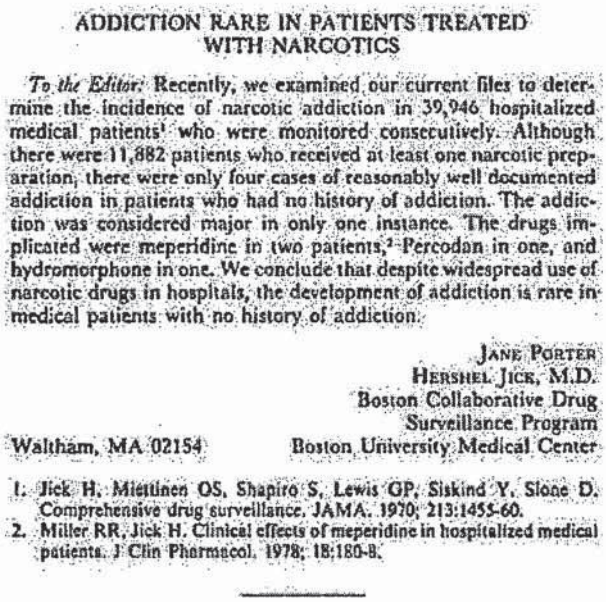
[90] FDA announces safety labeling changes and post market study requirements for extended- release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).
[91] CDC Guideline at 21.
[92] *Id.* at 2.

part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine ("NEJM") in 1980.

247. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[93] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Boston University Medical Center
Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind V, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

248. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[94]

[93] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[94] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail Of Addiction And Death*, 174 (Rodale 2003) (herein after "Pain Killer").

249. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[95] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

250. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos states "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%.*"[96] Purdue trained its sales representatives to tell prescribers that less than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[97]

251. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction

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[95] J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).
[96] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI, (last accessed August 1, 2018) (emphasis added).
[97] Patrick R. Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

> was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[98]

252. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[99]

253. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[100]

254. Abbott sales staff were instructed with respect to euphoria patients were receiving on the shorter-acting painkiller Vicodin, they should tell the physician that "OxyContin has fewer such effects." Abbott's "King of Pain" taught his staff of "Royal Crusaders" that OxyContin would "minimize[e] the risk of dependence" and "lower[] euphoria," when, in fact, he had little knowledge of pharmacology and no basis for these statements.

255. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are

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[98] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

[99] *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

[100] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[101]

256. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.* In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?" Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

257. Sales representatives marketed OxyContin as a product "to start with and to stay with."[102] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[103] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[104]

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[101] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG- 107hhrg75754.htm.
[102] Keefe, *Empire Of Pain, supra* n. 97.
[103] *Pain Killer, supra* n. 94, at 102.
[104] *Id.*

258. Purdue, through its unbranded website *Partners Against Pain*,[105] stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids."

259. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[106] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

260. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

261. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated

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[105] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

[106] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

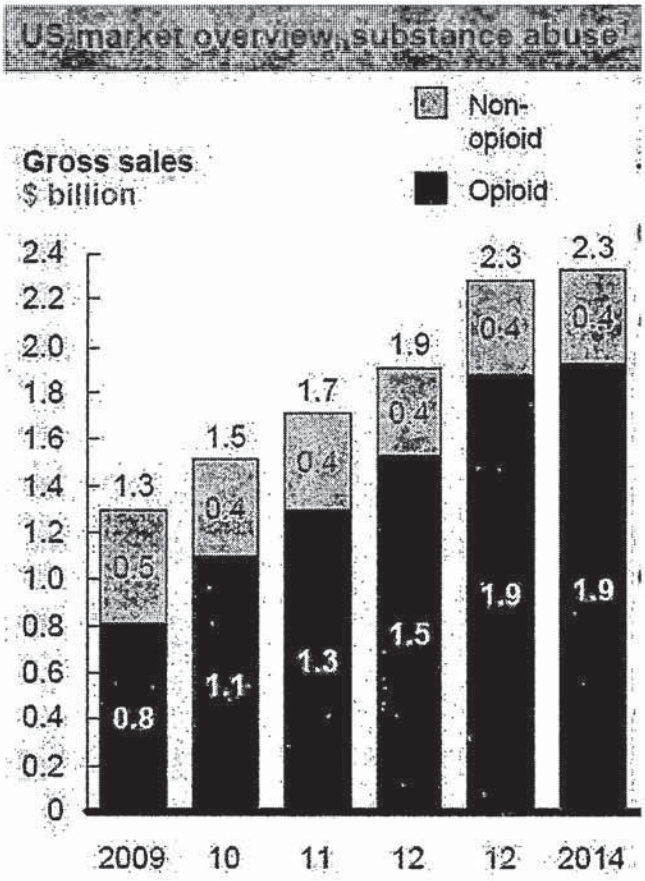
262. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

263. In 2001, Purdue revised the indication and warnings for OxyContin.

264. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

265. The Purdue Conspirators' awareness of the addictive properties of their opioid products is best exemplified by their cynical attempts to profit from addiction treatment. In 2007, Richard Sackler filed an application for a patent for a purported treatment for opioid addiction. In September 2014, Kathe Sackler dialed in to a confidential call about Project Tango -- a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Kathe and staff wrote down what Purdue publicly denied for decades: that addictive opioids and opioid addiction are "naturally linked." They determined that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain provider." Purdue illustrated the end-to-end business model with a picture of a dark hole labeled "Pain treatment" that a patient could fall into — and "Opioid addiction treatment" waiting at the

bottom. Kathe and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014:



Purdue's measure of the opioid addiction "market"

266. Kathe and the staff found that the catastrophe provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010." Kathe and the staff revealed in their internal documents that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids.

- *"This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor"*

Purdue's "Project Tango" patient and clinical rationale

267. Kathe and the staff concluded that millions of people who became addicted to opioids were the Sackler Co-Conspirators' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients *on* opioids could now be used to sell treatment for opioid addiction.

268. In June 2017, the Sackler Co-Conspirators met to discuss a revised version of *Project Tango* - another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

2. Endo's Misrepresentations Regarding Addiction Risk

269. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

270. Until April 2012, Endo's website for Opana, *www.opana.com*, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

271. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

272. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below.

273. APF conveyed through its National Initiative on Pain Control ("NIPC") and its website *Painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

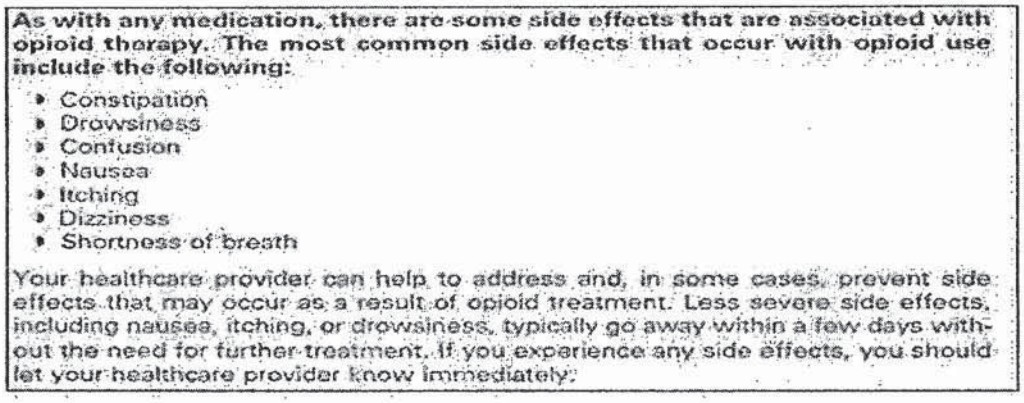
274. Another Endo website, *www.PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

275. A brochure available on *www.Painknowledge.com* titled "*Pain: Opioid Facts*," an Endo- sponsored NIPC, stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

276. In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online and was edited by KOL Dr. Russell Portenoy[107].

[107] Margo McCaffery, RN MS, FAAN & Chris Pasero, RN, MS FAAN, *Understanding Your Pain, Taking Oral Opioid Analgesics*, http://www.thblack.com/links/rsd/understand_pain_opioid_analgesics.pdf (last accessed October 26, 2018)

277. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *www.Painknowledge.com*, omitted addiction from the "common risks" of opioids, as shown below:



As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

3. Janssen's Misrepresentations Regarding Addiction Risk

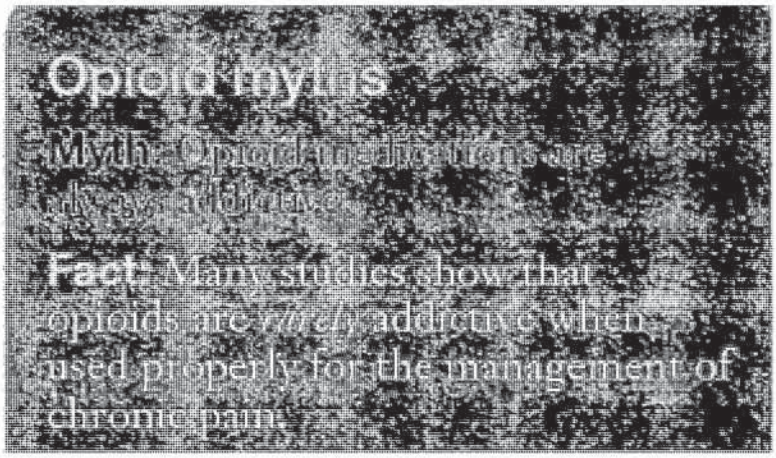
278. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding addiction."

279. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

280. A Janssen unbranded website, *www.PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[108]

[108] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).

281. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." (emphasis in original). Until recently, this guide was still available online.



282. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

4. Cephalon's Misrepresentations Regarding Addiction Risk

283. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options*: *A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

284. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the non-cancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[109]

5. Mallinckrodt's Misrepresentations Regarding Addiction Risk

285. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

286. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company.

[109] Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, http://www.medscape.org/viewarticle/449803, (last accessed July 27, 2017).

Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

287. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy." "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

c. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

d. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

e. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

f. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

288. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain* and *Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

289. Marketing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

B. Falsehood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

290. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

291. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials.

292. Janssen, on its website *www.PrescribeResponsibly.com*, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between

patients and doctors.[110] The website, which directly provides screening tools to prescribers for risk assessments,[111] includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.[112]

293. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed" and counseled patients that opioids "give [pain patients] a quality of life we deserve."

294. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

295. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

296. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and

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[110] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction (last modified July 2, 2015).
[111] Risk Assessment Resources, http://www.prescriberesponsibly.com/risk-assessment-resources (last accessed August 1, 2018).
[112] *Id.*

other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

297. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care*: *Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

298. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

C. Falsehood #3: Signs of Addictive Behavior are "Pseudoaddiction," Requiring More Opioids

299. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as

"the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[113] In other words, people on prescription opioids who exhibited classic signs of addiction— for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

300. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

301. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

302. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain:

> A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may 'clock watch," and may otherwise seem inappropriately "drug-seeking.' Even such behaviors as illicit drug use and deception can occur in the patient's efforts to

[113]David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565. ("Iatrogenic" describes a condition induced by medical treatment.)

> obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

303. Purdue again urged doctors to prescribe higher doses, stating that opioids "are frequently underdosed - or even withheld due to a widespread lack of information … about their use among healthcare professionals."

304. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's *Pain Management Kit* is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming "pain-relief seeking behavior can be mistaken for drug-seeking behavior." In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the kit was in use from roughly 2011 through at least June 2016.

305. A Purdue presentation for doctors titled *Medication Therapy Management* recited what had been the consensus view for decades: "Many medical students are taught that if opioids are prescribed in high doses or for a prolonged time, the patient will become an addict." Purdue then assured doctors that this traditional concern about addiction was wrong — that patients instead suffer from "pseudoaddiction" because "opioids are frequently prescribed in doses that are inadequate." Doctors on Purdue's payroll admitted in writing that pseudoaddiction was used to describe "behaviors that are clearly characterized as drug abuse" and put Purdue at risk of "ignoring" addiction and "sanctioning abuse." Purdue, nevertheless, urged doctors to respond to signs of addiction by prescribing higher doses of Purdue's drugs.

306. Purdue publications touting the concept of "pseudoaddiction" were regularly provided to the Purdue Individual Defendants by Purdue staff. Staff also regularly reported on the distribution of such materials to the Purdue Individual Defendants.

307. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

308. Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[114] Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

309. The FAQs section of *www.pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes

[114] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

310. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012. Janssen also currently runs a website, *www.Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases."[115]

311. The CDC Guidelines nowhere recommend attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

D. <u>Falsehood #4: Blaming Addicted Patients as "Untrustworthy" "Abusers"</u>

312. A recurring strategy employed by the Purdue Individual Defendants, over a period of decades, was to blame any negative consequences from opioid use on moral failings of a minority of users, who would be labeled as "abusers" or "untrustworthy" people.

313. In 2001, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. Sackler

[115] Howard Heit, MD, FACP, FASAM, & Douglas Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids, (last accessed July 16, 2018).

wrote in a confidential email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." The Sackler Co-Conspirators chose to stigmatize people who were hurt by opioids, calling them "junkies" and "criminals."

314. In December 2011, John Stewart gave a speech titled Providing Relief, Preventing Abuse in Connecticut, which deceptively blamed the addiction, overdose, and death on "abuse." A Purdue pamphlet entitled *Responsible Opioid Prescribing* told doctors that only "a small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for addictive opioid drugs.

315. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to "trustworthy" patients was safe. A sales rep reported that one doctor: "let me know that she will Rx OxyContin when the pts [patients] has chronic pain and are trustworthy." The rep added that he would "Follow up with Dr and ask what pts does she consider 'trust worthy?'" A Purdue district manager responded: "Great follow up question on what patients does he consider trustworthy." Purdue managers praised sales reps for pitching doctors on the idea that prescribing to "trustworthy" patients was safe.

316. Richard Sackler, in a 2007 patent application he filed for a purported treatment for opioid addiction, referred to addicts as "junkies." In the application, he asks for a monopoly on the treatment of addicts. He received the patent in January 2018.

E. Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering

317. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient's dose to avoid the adverse effects of

withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

318. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.

319. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

320. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

F. Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk

321. In materials they produced, sponsored or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses that were confirmed by scientific evidence.

322. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are much more likely to remain on opioids for a longer period of time, resulting in increased revenue.

323. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were more expensive and increased the likelihood of addiction.

324. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

325. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be

increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[116]

326. Purdue, for years, used a marketing theme dubbed "Individualize the Dose," which was a euphemism for "Increase the Dose," as a means of propounding the false notion that increasing doses of painkillers was in patients' best interests. Staff regularly reported to the Sackler Co-Conspirators that Purdue's sales representatives were continuing the *Individualize the Dose* campaign.

327. Endo sponsored a website, *www.Painknowledge.com*, which claimed that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

328. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased . . . You won't 'run out' of pain relief."

329. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

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[116] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://web.archive.org/web/2/https://www.fda.gov/downloads/Drugs/DrugSafet%20y/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf, (last modified Nov. 2010).

G. Falsehood #7: Long-term Opioid Use Improves Functioning

330. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids for patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

331. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

332. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine…We do not have such data to support OxyContin promotion . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[117]

333. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your

[117] *Pain Killer*, *supra* n. 94, at 281.

November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[118]

334. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

335. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

336. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *www.opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

337. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that,

[118] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

"[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

338. In addition, Janssen's *Let's Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

339. Endo's NIPC website, *www.Painknowledge.com*, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

340. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

341. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[119]

[119] Mallinckrodt Pharmaceuticals, Responsible Use, http://www.mallinckrodt.com/corporate-responsibility/responsible-use, (last accessed July 16, 2018).

342. The Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[120] Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[121]

343. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that Opioids for chronic pain may actually worsen pain and functioning . . ."[122] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

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[120] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[121] CDC Guideline at 20.

[122] Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374New Eng. J. Med., 4/21/16, at 1503. (April 21, 2016).

344. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[123] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[124]

345. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[125] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[126] Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than

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[123] CDC Guideline at 2, 18.
[124] Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (AprilApr. 21, 2016), doi: 10.1056/NEJMp1515917, http://www.nejm.org/doi/full/10.1056/NEJMp1515917.
[125] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747
[126] Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

workers with similar injuries who received no opioids at all.[127] Yet, Marketing Defendants have not acknowledged, retracted, or corrected their false statements.

H. Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

346. In materials they produced, sponsored or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs ("NSAIDs").

347. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, the Marketing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[128] hormonal dysfunction;[129] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[130] NAS (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines,

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[127] Franklin, GM, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, https://www.ncbi.nlm.nih.gov/pubmed/18197107.

[128] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[129] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), https://www.ncbi.nlm.nih.gov/pubmed/14622741.

[130] *See* Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32 (July 31, 2014), doi: 10.1093/eurpub/cku120, https://www.ncbi.nlm.nih.gov/pubmed/25085470.

which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[131]

348. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is actually closer to 3,200.[132]

349. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

350. Endo's NIPC website, *www.Painknowledge.org*, contained a flyer called "Pain: Opioid Therapy." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

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[131] Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, https://jamanetwork.com/journals/jama/fullarticle/1105046.

[132] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), https://www.ncbi.nlm.nih.gov/pubmed/14704592.

351. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[133] The article asserted:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[134]

352. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

353. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

354. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and

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[133] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf, (link no longer available).
[134] *Id.*

acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[135]

I. Falsehood #9: OxyContin Provides Twelve Hours of Pain Relief

355. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

356. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.

[135] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). "For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady.." *See also*, J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

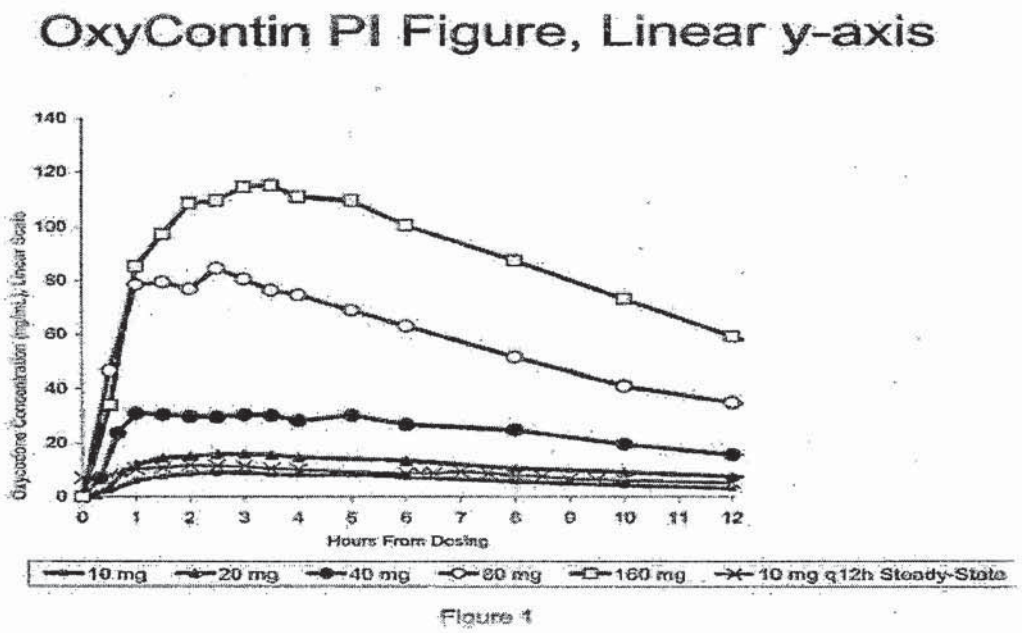


Figure 1

357. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

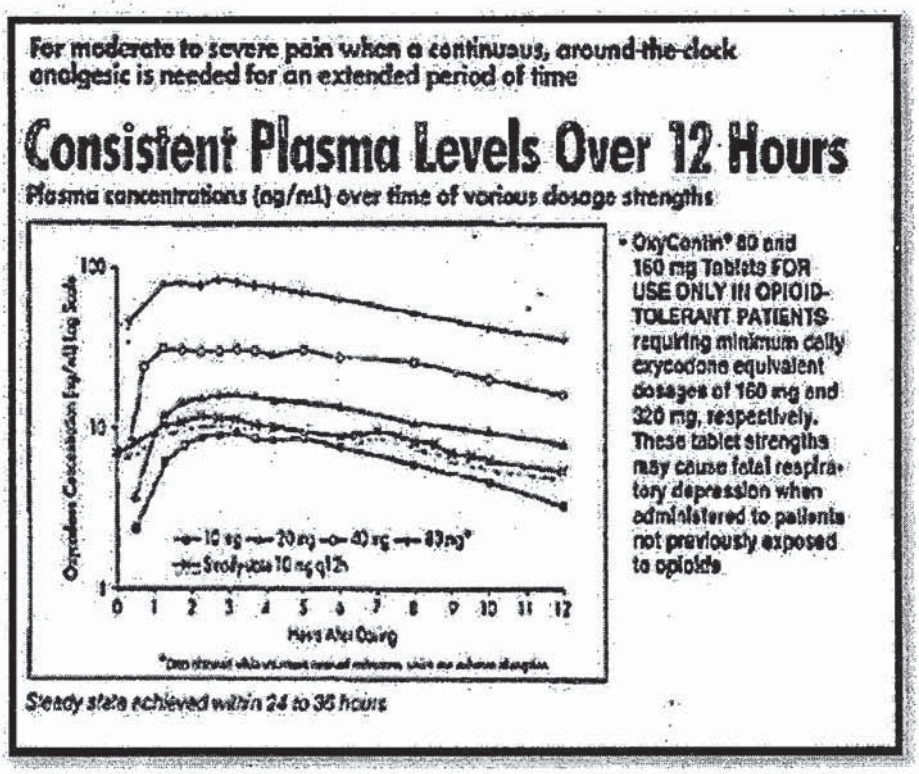
358. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

359. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[136] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall quantity of opioids they are taking.

360. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

361. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

[136] Harriet Ryan, et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.



362. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[137]

363. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push

[137] Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), http://documents.latimes.com/oxycontin-launch-1995/.

higher-strength pills, even though higher dosing carries its own risks, as noted above. Higher Dosing also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[138]

364. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two is apparent from MEDWATCH Adverse Event reports for OxyContin.

365. Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

366. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses."[139] One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud. NOW!!"[140]

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[138] CDC Guideline at 16.
[139] Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/
[140] Harriet Ryan, et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

367. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the true effects of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

J. Falsehood #10: New Formulations of Certain Opioids Successfully Deter Abuse

368. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as an opportunity to compete. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

369. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

1. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER

370. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

371. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

372. Internal documents reveal that the Purdue Individual Defendants knew, and in fact discussed, the fact that the "crush-proof" ADF reformulation would not prevent the vast majority of opioid abuse, which comes from swallowing pills, and that they introduced the product solely for purposes of extending their patent. In 2008, John Stewart, then CEO, wrote to Richard Sackler that reformulating OxyContin "will not stop patients from the simple act of taking too many pills."

373. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

c. asserted or suggested that its ADF opioids are non-addictive or less addictive;

d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and

e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

374. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

375. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

376. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

377. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including

heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to abuse the drug orally after the reformulation rather than shift to other drugs.

378. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The article revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

379. Websites and message boards used by drug abusers, such as *bluelight.org* and *reddit.com*, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

380. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

381. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated

product has a meaningful impact on abuse."[141] In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

382. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

2. Endo's Deceptive Marketing of Reformulated Opana ER

383. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

[141] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

384. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

385. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent.

386. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

387. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, the amount Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[142] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[143]

388. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version

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[142] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).
[143] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[144]

389. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[145]

390. However, in a 2013 decision rejecting the petition, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

391. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER has increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[146] The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of

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[144] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).
[145] CP, FDA Docket 2012-8-0895, at 2.
[146] Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014)), https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/.

HIV, hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

392. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Ohio from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

393. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

394. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

395. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers. The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo

press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

396. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

397. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of Opana,[147] the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required "that Endo Pharmaceuticals remove [Opana ER] from the market." The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[148]

398. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.[149] Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.[150]

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[147] Press Release, State of Ind. Health Dep't, HIV Outbreak in Southeastern Indiana, (Feb. 25, 2015), http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information_id=211489.

[148] Jen Christensen, *FDA wants Opioid Painkiller Pulled off Market,* CNN (June 8, 2017), https://www.cnn.com/2017/06/08/health/fda-opioid-opana-er-bn/index.html; Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.; FDA Requests Removal of Opana ER, *supra* n. 67.

[149] FDA Requests Removal of Opana ER, *supra* n. 67.

[150] Press Release, Endo International plc, Endo Provides Update on Opana ER, (July 6, 2017), *available at* https://www.prnewswire.com/news-releases/endo-provides-update-on-opana-er-300484191.html.

However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

3. Other Marketing Defendants' Misrepresentations Regarding Abuse Deterrence

399. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[151] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."

400. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[152] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[153]

401. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of

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[151] Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), *available at* http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.
[152] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).
[153] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/

abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

402. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants' misrepresentations and omissions as set in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.

II. The Marketing Defendants Directly Targeted Hospitals

403. From the beginning, hospitals were directly targeted by the Marketing Defendants. Internal documents from the 1995 "OxyContin Launch" orchestrated by Defendants Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months," and (4) identified an objective of developing a "successful distribution program" to "hospitals."

404. In 1996, Purdue made a deal with Defendant Abbott under which Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals. Abbott's co-promotion of OxyContin was, in the words of Abbott's counsel, by terms of its contract, dedicated to "hospitals, surgical centers and hospital-based surgeons." Promoting the use of OxyContin for "postoperative pain" and "support[ing] the Abbott agreement" were paramount objectives identified in Purdue's internal documents. "Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy

and Therapeutic (P&T) communities." "[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies."[154]

405. Initial plans called for marketing to "[a]ll 1,200 cancer centers," "[a]ll 1,200 major teaching institutions," and "[a]ll 2,500 community hospitals with >= 100 beds." The hospital marketing plan further entailed the following actions:

a. The Purdue Frederick sales force should call on all hospital P&T committees to gain hospital formulary acceptance during the first three months of launch. This effort would entail contacting directors of pharmacies in an effort to gain formulary acceptance of OxyContin.

b. Educate MD's/RN's/RPH's regarding the advantages of OxyContin over other Step 2 opioids for cancer patients. The promotional effort should focus on the ease of use and the reduced administration time. If available, clinical outcomes studies, showing improved quality of life and cost effectiveness, should be used to convince the house staff to use OxyContin as their opioid of choice.

c. Educational lectures should be held through the Speakers' Bureau program during grand rounds, tumor boards, etc. The Purdue Frederick Speakers' Bureau should educate the house staff about the benefits of OxyContin, while presenting clinical study data.

d. Educational symposia should be conducted through the use of satellite teleconferencing to various cancer centers and major teaching institutions across the country, offering CME credits to MD's/RN's/RPH's and focus on the implementation of the AHCPR Clinical Practice Guideline for the Management of Cancer Pain and the results of clinical trials with OxyContin.

e. Target the top 100 MS CONTIN/Duragesic hospitals and offer them a special pain management day where our OxyContin clinical investigators will train the staff on the use of OxyContin.

406. Defendant Abbott, in a 1997 document, indicated that prescriptions written by "Abbott MD's" comprised 25% of all OxyContin prescriptions. In addition, Purdue's budget records reveal details of the payments to Abbott for its OxyContin work, which were termed "commissions." From 1996 through 2002, Abbott was paid $374 million in commissions,

[154] 2002 Purdue Budget Plan, https://khn.org/news/purdue-and-the-oxycontin-files/ (last accessed Aug. 20, 2018) (emphasis added).

according to those documents. Total sales of the drug during that time were nearly $5 billion. From 2003 to 2006, OxyContin sales were nearly $6 billion. From 1996 to 2005, inclusive, Abbott's "commissions" exceeded $500 million.

407. The importance of targeting hospital emergency rooms was illustrated by a study that demonstrated that patients who receive an opiate prescription within 7 days of surgery are 44% more likely to still be using the medication one year after surgery than patients who do not receive an opioid prescription."[155]

III. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels

408. The Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the country, including those communities served by Plaintiffs.

409. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by the drug manufacturers' corporate headquarters. This comprehensive approach ensures that the Marketing Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

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[155] Cheryl Genord et al., *Opioid exit plan: A pharmacist's role in managing acute postoperative pain*, Journal of the American Pharmacists Association (Jan. 2017), at 593, *available at* https://www.japha.org/article/S1544-3191(17)30016-X/fulltext (hereinafter "Opioid Exit Plan").

410. The Marketing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

411. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) direct, targeted communications with prescribers by sales representatives or "detailers;" (2) "Front Groups" with the appearance of independence from the Marketing Defendants; (3) so-called KOLs, that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (4) disseminating their misleading messages through reputable organizations; (5) CME programs controlled and/or funded by the Marketing Defendants; (6) branded advertising; (7) unbranded advertising; (8) publications; and (9) speakers bureaus and programs.

A. The Marketing Defendants Used "Detailers" To Directly Disseminate Their Misrepresentations to Prescribers

412. The Marketing Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive. The Marketing Defendants' direct contact with prescribers was, by far, their most

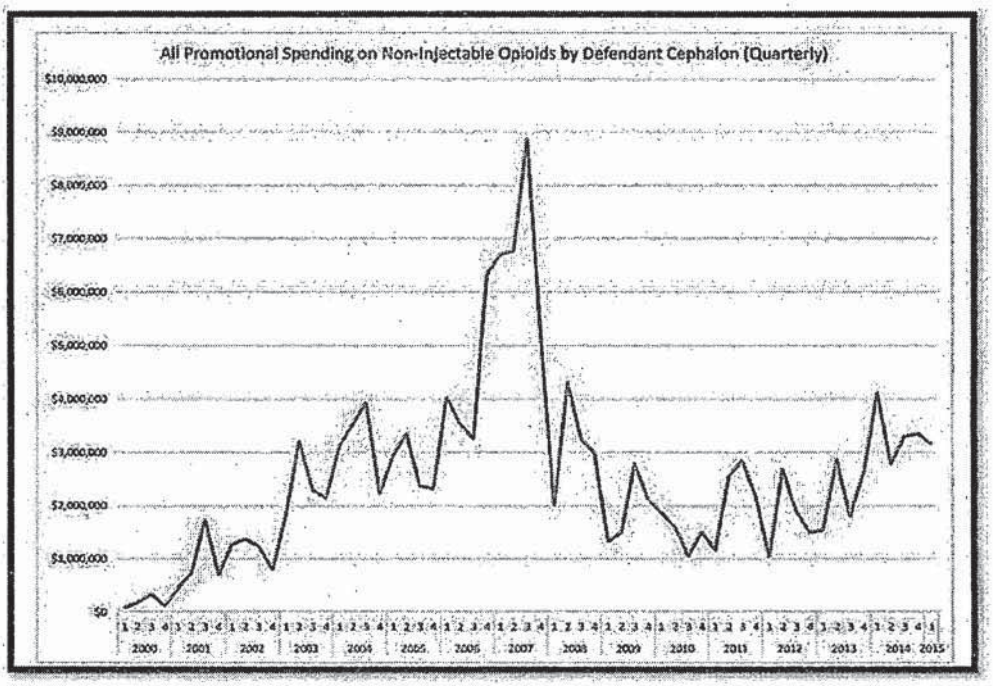
important means of disseminating the false narrative and increasing opioid prescriptions, and, accordingly, their sales.

413. Each Marketing Defendant promoted opioids through sales representatives (also called "detailers") and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that small group speaker programs were designed to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

414. In accordance with common industry practice, the Marketing Defendants purchased and closely analyzed prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allowed them to precisely track the rates of initial and renewal prescribing by individual doctors, which allowed them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

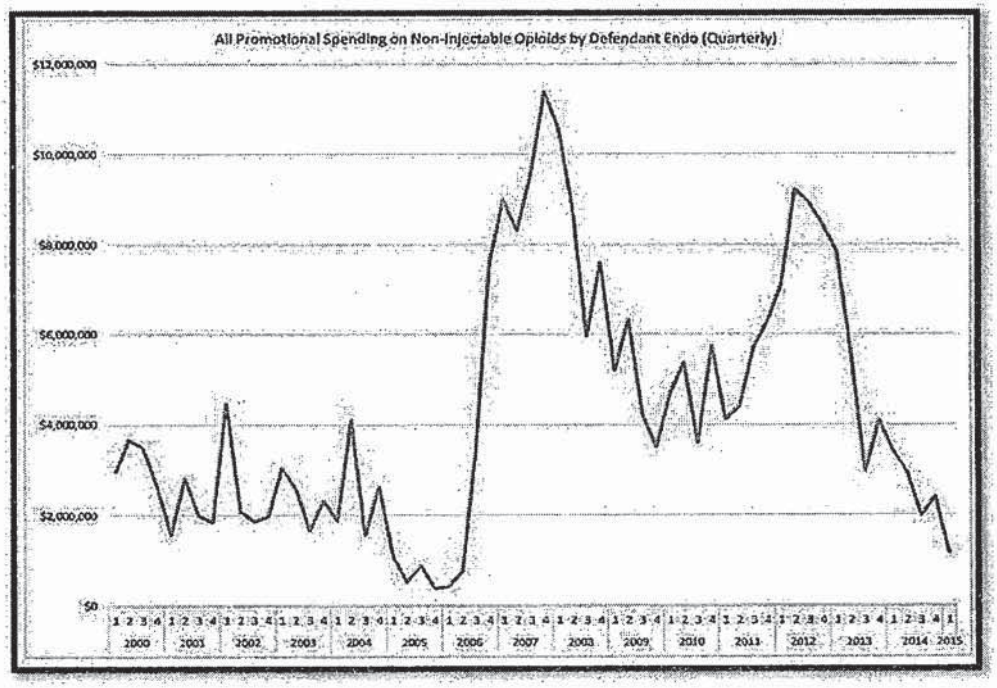
415. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

416. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:

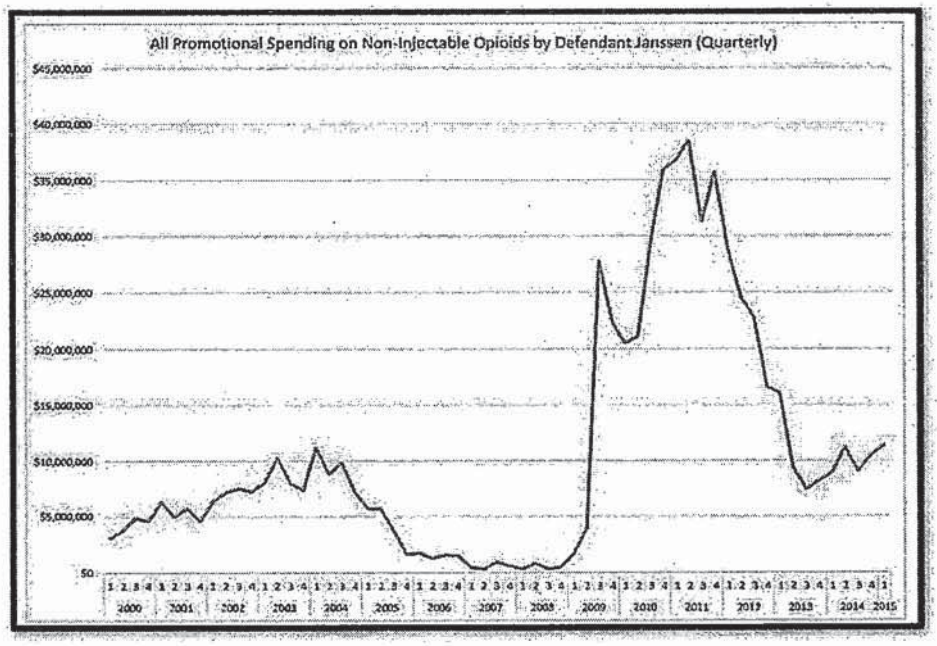


417. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

418. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year), as shown below:



419. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



420. Abbott, which was tasked with marketing Purdue's products to hospitals, heavily incentivized its staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers. Abbott's almost religious zeal to sell the drug is evident in the wide use of terminology from the Middle Ages Crusades: Sales reps were called "royal crusaders" and "knights" in internal documents, and they were supervised by the "Royal Court of OxyContin" – executives referred to in memos as the "Wizard of OxyContin," "Supreme Sovereign of Pain Management," and the "Empress of Analgesia." The head of pain care sales, Jerry Eichhorn, was the "King of Pain," and signed memos simply as "King."

421. At Purdue, aggressive and frequent visits to prescribers was always its most important marketing technique. The Sackler Co-Conspirators set targets for each representative to visit over 7 prescribers per day, and closely monitored actual data. Some doctors were visited multiple times per week. The pressure on sales representatives, and on prescribers, was relentless, and was dictated by the Sackler Co-Conspirators.

422. Each of these in-person sales visits cost Purdue money — on average more than $200 per visit. But Purdue made that money back many times over, because it convinced doctors to prescribe its addictive drugs. When Purdue identified a doctor as a profitable target, including several targets in Mississippi, Purdue visited the doctor frequently: often weekly, sometimes almost every day. Purdue salespeople, including the Purdue Sales Representative Defendants Grace, Gatling and Roberson, asked doctors to list specific patients they were scheduled to see and pressed the doctors to commit to put the patients on Purdue opioids. By the time a patient walked into a clinic, the doctor, in Purdue's words, had already "guaranteed" that he would prescribe Purdue's drugs.

423. Purdue judged its sales representatives by how many opioids they got doctors to prescribe. Sales representatives who generated the most prescriptions won bonuses and prizes. These incentives included a "Toppers Club sales contest" for sales representatives to win bonuses, based on how much a representative increased OxyContin use in her territory and how much the representative increased the broader prescribing of opioids — the same "availability of product" and "prescribing practices" factors that worsen the risk of diversion and abuse. Purdue also maintained a "President's Club Leaders Board" for Hysingla ER, indicating which territory brand managers had been most successful in meeting marketing objectives.

424. Purdue continued to incentivize its representatives to sell opioids even after some competitors had ended that practice. Representatives who failed to get enough patients on opioids were placed on probation, put on performance improvement plans, and they would be threatened with loss of their jobs if they did not generate more opioid sales. Those unable to generate more sales were fired. In 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its District Managers for failing to create enough opioid sales.

425. Sales representatives focused on prolific (and potentially prolific) prescribers, described internally at Purdue as "core," "super core," and "high potential" prescribers at times, even though the Marketing Defendants were all well aware of the heightened risk of improper prescriptions and diversion through these prescribers. Non-Party Richard Sackler once chastised his senior marketing officer Russell Gasdia for Purdue's managers permitting sales representatives to target "non-high potential prescribers," asking "[h]ow can our managers have allowed this to happen?" Richard Sackler personally insisted that sales representatives push the doctors who prescribed the most drugs.

426. To make sure doctors prescribed more opioids, Purdue tracked doctors' prescriptions, visited their offices, bought them meals, and asked them to put specific patients on Purdue drugs. Purdue selected doctors for target lists based on its estimates of which doctors could be influenced to increase opioid prescriptions the most. Purdue managers told representatives to visit most often the doctors who were most likely to change their prescribing to benefit Purdue. Purdue Sales representatives, including the Purdue Sales Representative Defendants, visited Purdue's targets, including top targets in Mississippi, an average of more than 200 times per year ***each***. Those visits cost Purdue more than $40,000 for each doctor. Purdue did not spend $40,000 per doctor so sales representatives could watch doctors write prescriptions that they were already going to write anyway. Instead, Purdue paid to lobby these doctors because Purdue knew its representatives would convince them to put more patients on opioids, at higher doses, for longer periods. Those extra prescriptions paid back Purdue's investment many times over.

427. Compared to Mississippi doctors and nurses who prescribed Purdue opioids without lobbying from sales reps, Purdue's top targets wrote far more dangerous prescriptions.

Purdue's top targets prescribed Purdue opioids to more of their patients, at higher doses, and for longer periods of time. Compared to Mississippi doctors and nurses who prescribed Purdue opioids without seeing reps, Purdue's top targets were ***at least ten times more likely*** to prescribe Purdue opioids to patients who overdosed and died.

428. As of the fourth quarter of 2013, Purdue employed 632 sales representatives (including the Purdue Sales Representative Defendants Grace, Gatling, and Roberson) and, during that quarter they visited prescribers 176,227 times – an annualized rate of over 700,000 visits. These statistics, including statistics specific to Mississippi, were regularly reported to the Sackler Co-Conspirators and Purdue Officer Co-Conspirators. Purdue's budget for Sales and Promotion for 2013 was $312,563,000. In 2013, Purdue spent over $9 million on meals alone for its prescribers.

429. The sales visits of its staff were so important to the Sackler Co-Conspirators that Non-Party Richard Sackler himself went into the field in 2013 to promote opioids to doctors alongside a sales representative. Russell Gasdia and Purdue's Chief Compliance Officer were well aware that this was "a potential compliance risk." To make sure the Sackler Co-Conspirators involvement in marketing stayed secret, staff instructed: "Richard needs to be mum and be anonymous." When he returned, Richard Sackler argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard Sackler insisted there should be "less threatening" ways to describe Purdue opioids.

430. Purdue intensified its marketing efforts in subsequent years, in an effort to counteract decreasing sales (sales of OxyContin peaked in 2010, and decreased somewhat in subsequent years). For 2018, the Sacklers approved a target for sales representatives to visit

prescribers 1,050,000 times – which would include thousands of visits to Mississippi prescribers — almost double the number of sales visits they had ordered during the peak of OxyContin sales in 2010.

B. The Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use

431. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.[156] Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of the Front Groups own constituencies.

432. "Patient advocacy organizations and professional societies like the Front Groups 'play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'"[157] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[158]

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[156] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (FebruaryFeb. 12, 2018), https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at p. 3.
[157] *Id.* at p. 2.
[158] *Id.*

Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[159] which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of Office opioids policy,"[160] found that the Marketing Defendants made millions of dollars' worth of contributions to various Front Groups.[161]

433. The Marketing Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[162]

434. As the Senate's *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[163] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding."[164]

435. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their

[159] *Id.* at p. 1.
[160] *Id.*
[161] *Id.* at p. 3.
[162] *Id.* at p. 10.
[163] *Id.* at 12-15.
[164] *Id.* at 12.

false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each working with the other to deceptively promote the use of opioids for the treatment of chronic pain.

1. American Pain Foundation

436. The most prominent of the Front Groups was the APF. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

437. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed *supra*.

438. APF also developed the NIPC, which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional

education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

439. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "*Partners Against Pain*" and Janssen's "*Let's Talk Pain*." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that shared its business interests.

440. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

441. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason.

442. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. The

close relationship between APF and the Marketing Defendants demonstrates APF's lack of independence in its finances, management, and mission, and APF's willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions.

443. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

2. American Academy of Pain Medicine and the American Pain Society

444. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[165] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

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[165] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (last accessed August 1, 2018).

445. AAPM's corporate council includes Purdue, Assertio, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

446. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[166]

447. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

448. More specifically, Purdue paid $725,584.95 from 2012-2017 to AAPM.[167] Janssen paid $83,975 from 2012-2017 to AAPM.[168] Insys paid $57,750 from 2012-2017 to AAPM.[169] Endo funded AAPM CMEs. Teva is on AAPM's corporate relations council.

449. As to APS, Purdue paid $542,259.52 from 2012-2017.[170] Janssen paid $88,500 from 2012-2017.[171] Insys paid $22,965 from 2012-2017.[172]

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[166] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* http://www.medscape.org/viewarticle/500829.
[167] *Id.*
[168] *Fueling an Epidemic Part Two.*
[169] *Id.*
[170] *Fueling an Epidemic Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocary Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee,

450. AAPM describes its annual meeting as an "exclusive venue" for offering CME programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

451. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

452. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011.

453. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

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https://www.hsdl.org/?abstract&did=808171 (last accessed August 1, 2018) (hereinafter referred to as "*Fueling an Epidemic Part Two*")

[171] *Id.*

[172] *Id.*

454. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

455. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, and whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

456. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[173]

457. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

458. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines

[173] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, (March 15, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm, (hereinafter "2016 CDC Guideline").

while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

3. FSMB

459. The Federation of State Medical Boards (FSMB) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

460. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

461. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines—that the pharmaceutical companies helped author—taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

462. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Jackson County.

463. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid $100,000 for printing and distribution of FSMB's Guidelines.[174]

464. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards.[175] The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.[176]

465. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

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[174] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256.
[175] Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf.
[176] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).